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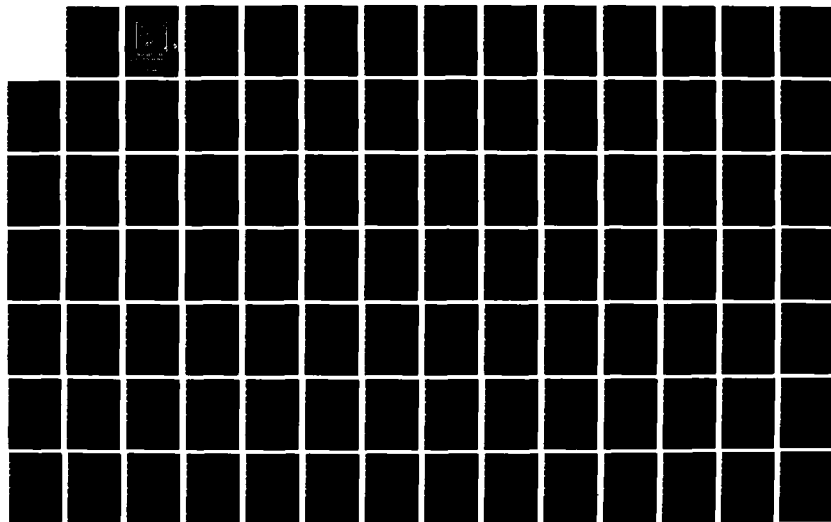
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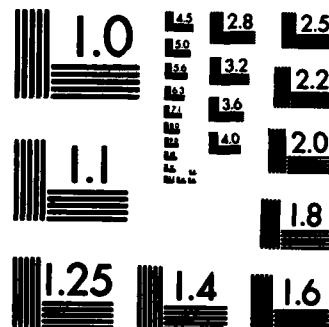
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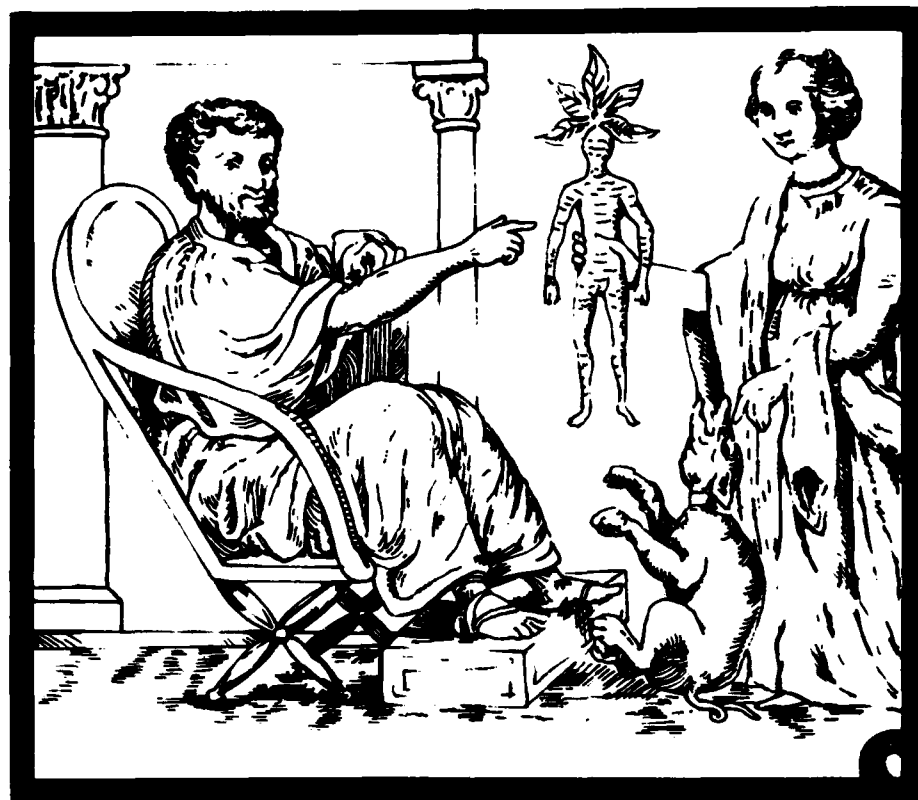
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CLINICAL · INVESTIGATION PROGRAM · REPORT



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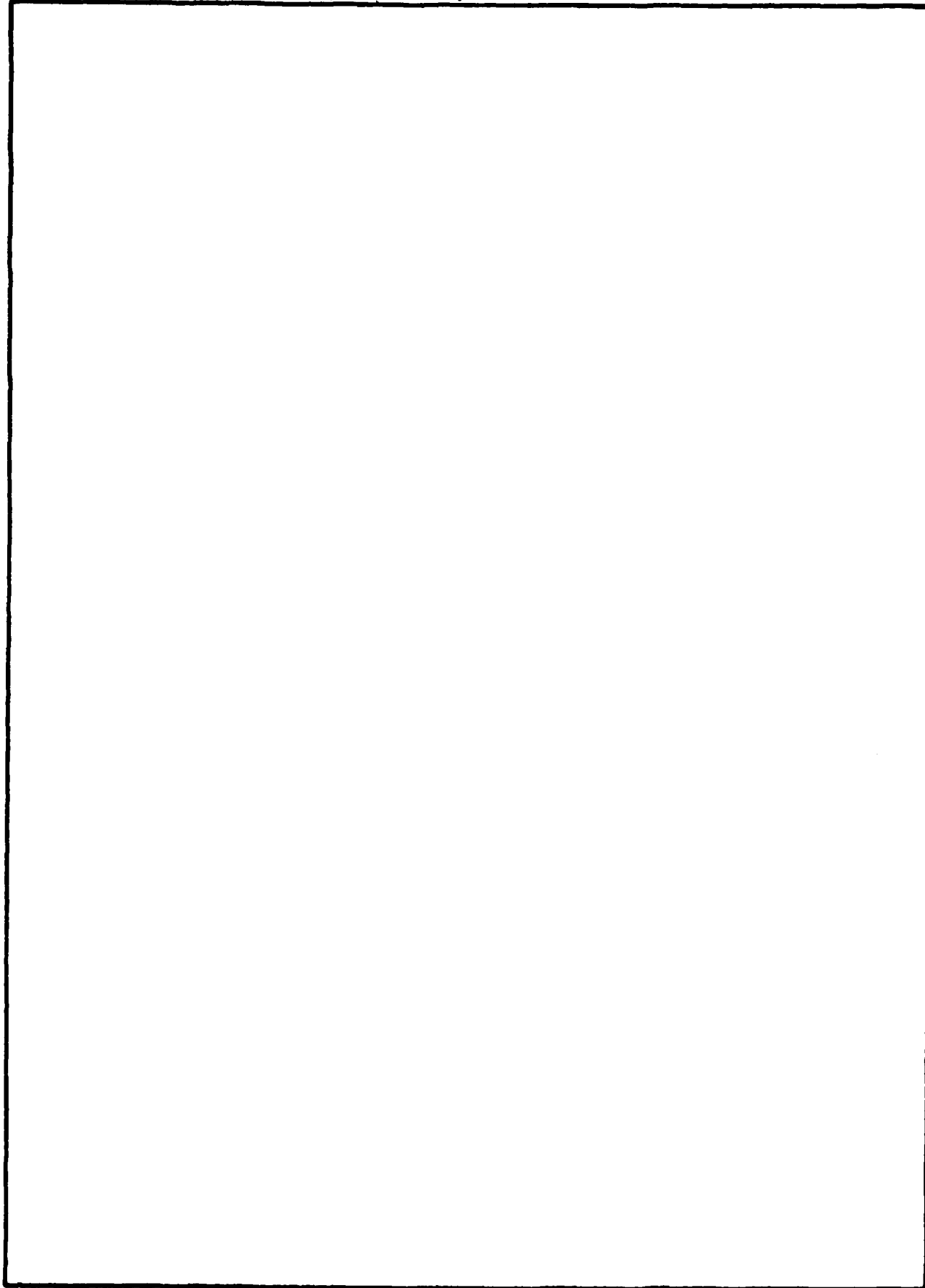
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19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Unit Summary; Detail Sheet (Study Objective, Technical Approach, Progress, Status); Publications; Presentations.		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Subject report identifies the research activities conducted by Dwight David Eisenhower Army Medical Center investigators through protocols approved by the Institutional Review Committee for registration with the Department of Clinical Investigation during Fiscal Year 1984, and other known publications and pre- sentations by the Dwight David Eisenhower Army Medical Center professional staff. A detail sheet of each protocol giving the objective, technical approach, and progress is presented.		

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FOREWORD

The print featured on this year's cover depicts the Roman physician, Dioscorides, as he receives the mandrake plant from the goddess of discovery. His materia medica was to be the standard of quality for medical botany until well into the medieval period. He accomplished this prodigious task while traveling as a Roman army surgeon. His collection included a vast range of plant, animal, and mineral substances. Through experimentation and careful documentation, he established many of their pharmacologic properties. In fact, nearly 100 of the 600 plants detailed by him are still worthy of mention in modern pharmacopoeia.

"Discovery's" presence is obviously symbolic inasmuch as Dioscorides' diligent efforts can be credited for most of his success. He exemplified the adage, "Chance favors the prepared mind." As today, the diligent medical experimenter must know from dint of strenuous effort that "discovery" cannot be recognized by one who has not assiduously sought her in the night watches and learned her many guises.

With the role of animals in research being raised to greater public scrutiny, of late, a comment should be made regarding the dog's presence in the depicted scene. In this instance the dog was used to pull the mandrake from the ground so that the man-shaped root would retain its purported properties.

More commonly animals were used by the ancients in medicine much like the modern searchers of "discovery." The great Roman physician, Galen, who had toured all of the world's major medical centers, took a job at a gladiatorial amphitheater. Since he could not dissect humans, he supplemented his anatomical knowledge by dissecting animals, including even an elephant and a hippopotamus. He had claimed that a doctor without a knowledge of anatomy was like an architect without a plan. Most of Galen's knowledge of anatomy came from dissecting the more prosaic pigs and monkeys. His treatises on anatomy and medicine dominated medical thought until late medieval times.

Another little known role of animals in advancing surgery, especially gynecologic surgery, in the 16th century, is attested to by the fact that cesarean section and bilateral ovariectomy were both performed initially by two different sow gelders on their own family members. Their success with pigs had provided the impetus to make the daring transition to beloved humans. Following these successes, several surgeons attempted the operations. A treatise was finally written late in the century by Francois Rousset after sufficient experience was gained with people.

Surgeries of all sorts prior to the last century were performed optimally using various mixtures of soporifics and analgesics such as nighshade family members (mandrake, henbane, or belladonna) and opiates. The profound sleep produced was well known from ancient times as was the narrow therapeutic range.

Describing the nightshade, the 16th century physician, de Laguna, quotes Dioscorides,¹ "a dram of the extract from the root when dissolved in wine produces fleeting images that please the senses, but if the dose be doubled it drives a man mad for three days; if the dose be quadrupled it can cause immediate death."

Opportunities for Army physicians remain even today. They range from improved use of nightshade alkaloids in combatting the modern weapon of organophosphate poisoning to finding advances in knowledge despite restrictions on certain animal experimentation. The irony for the modern Army physician in pursuit of "discovery" is that human experimentation is less restrictive than for domestic carnivores. Nonetheless, the quest for "discovery" requires innovativeness, persistence, and an ability to recognize her many disguises and sequestrations.

Clinical investigators at Dwight David Eisenhower Army Medical Center owe a debt of gratitude to our Commander, Brigadier General Alcide M. LaNoue, MC and to our Deputy Commander for Clinical Services, Colonel Warren A. Todd, MC for their breadth of vision in cultivating the future Dioscorides currently in training programs by supporting them with the opportunities to enter the quest.



KENT M. PLOWMAN, M.D., PhD
LTC, MC
Chief, Department of Clinical Investigation

1. Rothman T: "de Laguna's commentaries on hallucinogenic drugs and witchcraft in Dioscorides' materia medica." Bull Hist Med 1972, 46:562-567.

UNIT SUMMARY - FISCAL YEAR 1984

A. Objective.

The Department of Clinical Investigation is responsible to the Chief, Professional Services for providing the facilities and atmosphere of inquiry necessary to support and stimulate both basic and clinical medical investigation within DDEAMC.

B. Technical Approach.

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-38, AR 40-7, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

C. Staffing.

Name	Rank	MOS	Title
Plowman, Kent, M.	LTC	61F00	Chief
Arensman, John B.†	MAJ	64F00	Veterinarian
Yancey, Anthony	MAJ	64F00	Veterinarian
Hannan, Charles J., Jr.*	CPT(P)	68J00	Physiologist/Pharmacologist
Harris, Richard W.	CPT(P)	68A00	Microbiologist
Sherman, Richard A.	CPT(P)	68T9C	Psychobiologist
Losier, Andrew J., Jr.	E7	92B20	NCOIC
Hobbs, Carroll	SP5	92B20	Med Lab Sp
Brady, Anne V.**	SP5	01H20	Biol Sci Asst
Gauthier, Pete A.	SP4	92D10	Chem Lab Sp
Lugo, Jesus	SP4	92D10	Chem Lab Sp
Bilal, Omar	PVT	91T10	Animal Sp
McCullers, Manuela	PVT	91T10	Animal Sp
Horner, Jack A.	QM13	01301	Asst C, S. Res Histologist
McPherson, James C. III, PhD	GS11	01320	Biochemist
	GS9	00181	Psychology Technician
Prior, Robert	GS9	00644	Medical Technologist
Hinton, Alma	GS7	00404	Biological Lab Technician
Martinez, Rosina	GS6	01087	Editorial Assistant
Silas, Bill E.	GS5	07706	Animal Caretaker
Ferrell, Sandra	GS4	00312	Clerk Steno

*PCS Jul 84

**PCS Jul 84

†Retired Jul 84



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D. Funding.

Type	Fiscal Year 83	Fiscal Year 84
Civilian personnel to include benefits	191,084.00	165,175.00
Consumable supplies	84,395.00	87,534.00
Civilian contracts to include consultants	5,183.00	11,502.00
TDY*	3,670.00	6,000.00
Publications	1,145.00	2,102.00
Noninvestment equipment (Minor MEDCASE)		15,634.00
Other OMA	7,499.00	13,257.00
OMA Total		28,891.00
MEDCASE	134,000.00	117,778.00
Other	2,595.00	
Military	305,415.00	301,070.00
Total	729,986.00	748,943.00

*Includes Clinical Investigation personnel plus other paper presentations from Dwight David Eisenhower Army Medical Center.

E. Progress.

Protocol Disposition FY 84

	<u>Completed</u>	<u>Terminated</u>	<u>Ongoing to FY 85</u>
FY 78	-	1	2
FY 79	1	1	3
FY 80	-	-	2
FY 81	1	3	4
FY 82	6	3	10
FY 83	8	14	12
FY 84	14	2	65
	<u>30</u>	<u>24</u>	<u>98</u>

In addition to the above totals, 3 studies were transferred to Walter Reed Army Medical Center; 1 study is pending budget approval at HSC; and 2 domestic animal studies have been suspended.

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O - Ongoing
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P - Published
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PUBLICATIONS FY 84

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Code:

(C) - Results of clinical study

PRESENTATIONS FY 84

1984 Recipient of the Annual Resident Research Award: CPT Mike Tillirson, MC, Dept of Family Practice, for his paper entitled "Cross Reactivity of Fall Weed Pollens as Determined by RAST Inhibition Technique."

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McPherson JC III, McPherson JC Jr. Pharmacologic responses to some newer hyperlipemic agents (pluronic polyols). Ann Conf Regional Lipid, Cashiers, NC, Nov 1983. (C)

McPherson JC III, McPherson JC Jr. Apparent increased serum gastrin levels associated with hyperlipemia and normal gastric emptying. 7th Int Congress Endocrinology, Quebec City, Canada, Jul 1984. (C)

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McPherson JC Jr, McPherson JC III. Pharmacodynamic effects of intravenous pluronic polyols F-38, F-68, F-77, F-88, F-108, F-127 and P-105: Effects on serum lipids and other constituents. Soc Exper Biol Med, SE Section, Virginia Commonwealth University, Medical College of Virginia, Richmond, VA, Nov 1983.

Sherman RA, Tippens JK, Barja RH. Effectiveness of treatments for phantom limb pain. Soc Mil Orthop Surgeons, Colorado Springs, CO, Nov 1983. (C)

Sherman RA, Barja RH, Tippens JK. Surface Electromyographic Evaluation of chronic low back pain. Soc Mil Orthop Surgeons, Colorado Springs, CO, Nov 1983. (C)

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DEPARTMENT OF MEDICINE

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Morrison RE: Basic antibiotics. Medical College of Georgia, Augusta, GA, 15 Feb 1984 and 10 May 1984.

Jordan WT: Diabetes and the kidney. 6th Annual Regional Day in Medicine, Eisenhower Army Medical Center, Gt Gordon, GA, 9 Mar 1984.

Bennett RR. Determinants of the Effect of Dextrose on peritoneal permeability. IX International Congress of Nephrology, Los Angeles, CA, 11-16 Jun 1984.

Johnson WM: Occupational lung disease. Southeastern Occupational Health Conference, Columbia, SC, 11 Nov 1983.

DEPARTMENT OF NURSING

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Allanach BC. Nursing process survey: An evaluation of nurses attitudes and perceptions of nursing documentation. Phyllis J. Verhonik Nursing Research Course, Washington, DC, Sep 1984.

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

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Foreman A: Pregnancy and co-existent cancer. Medical College of Georgia, Augusta, GA, Apr 1984.

DEPARTMENT OF PEDIATRICS

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DEPARTMENT OF PSYCHIATRY AND NEUROLOGY

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Blum BN: Helping children diagnosed as learning disabled. Georgia Learning Resources Service and Richmond County Special Education, Augusta, GA, Sep 1984.

Bain MW: Reforging the child guidance concept: Reestablishing military child psychiatry services in Europe. Walter Reed Army Medical Center, Apr 1984.

Bain MW: Organizational aspects of hostage repatriation: The Iranian experience. Eisenhower Army Medical Center, Mar 1984.

Sechler EC: Speech and language development. Medical College of Georgia Wives Club, Augusta, GA, Oct 1983.

Sechler EC: Speech and language development and impairments. Parents Association of the Open Door Preschool. Augusta, GA, Mar 1984.

Sechler EC: Identification and management of speech and language problems in the preschool classroom. Teachers Inservice Training Program, Open Door Preschool. Augusta, GA Aug 1984.

Hoffer RS: Overcoming performance anxiety. Augusta Music Teacher's Association, Augusta College, Augusta, GA, Nov 1983.

Hoffer RS: The psychiatric consultant's approach to the chronic pain patient. The Reading Hospital and Medical Center. Reading, PA, Jun 1984.

Hoffer RS: The Army's leading killer. Eisenhower Army Medical Center, Sep 1984.

Wenner EJ Jr: Psychiatric management of deep vein thrombosis. American Academy of Physical Medicine and Rehabilitation and American Congress of Rehabilitative Medicine. Los Angeles, CA, Nov 1983.

SOCIAL WORK SERVICE

Maury JL: Child and family studies in social work fellowship. Current Trends in Army Social Work. Washington, DC, Nov 1983.

Maury JL: Effective family communications. St Teresa's Roman Catholic Church, Augusta, GA, Jan 1984.

Maury JL: The role of the volunteer: Issues of caring and confidentiality. Army Community Services, Ft Gordon, GA, Mar 1984.

Maury JL: Stress management. Army Community Services, Ft Gordon, GA, Jun 1984.

Jessie J: Family violence class. 2d Signal Bde Officers, Ft Gordon, GA, Jan 1984.

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Jessie J: Child abuse prevention campaign. All Officers and NCOs, Ft Gordon, GA, 16-19 Feb 1984.

Jessie J: Family violence. Military Officers and NCOS (Presented to 350 personnel) 9, 11, 12 Jul 1984.

DEPARTMENT OF SURGERY

Audiology

Bender DR, Mueller HG. User satisfaction with postauricular wireless CROS/BICROS amplification. Am Speech-Language Hearing Assn, Cincinnati, OH, Nov 1983. (C)

General Surgery Service

Belmont JR: Congenital laryngeal stridor-etiological factors and associated disorders. Am Bronchoesophagology Assn, West Palm Beach, FL, May 1984.
Seymour Cohen Award

Belmont JR: Treatment of large nasoseptal perforations and attendant nasal deformity. Am Acad Facial Plastic Reconstructive Surg, Las Vegas, Sep 1984.

Edwards FH: Computer assisted diagnosis of acute abdominal pain. Gary P. Wratten Surgical Symposium, WRAMC, Washington, DC, Apr 1984.

Opelka FG: Surgical therapy in acute pancreatitis. Gary P. Wratten Surgical Symposium, WRAMC, Washington, DC, Apr 1984.

Thomas RF: Angiodysplasia: A cause of lower gastrointestinal bleeding in the elderly. Gary P. Wratten Surgical Symposium, WRAMC, Washington, DC, Apr 1984.

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Martell JR. Technique of difficult intramedullary nail removal utilizing the MIDAS Rex. Soc Mil Orthop Surgeons, Colorado Springs, CO, Nov 1983.
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Fullerton LR. Mal-Union. Bone and Hand Pathology Symposium, Ft Gordon, GA, Jul 1984.

Goodrich JA. Infected Non-Union. Bone and Hand Pathology Symposium, Ft Gordon, GA, Jul 1984.

Young TR. Carpal joints instability. Bone and Hand Pathology Symposium, Ft Gordon, GA, Jul 1984.

Barja RH. Rheumatoid arthritis of the hand. Bone and Hand Pathology Symposium, Ft Gordon, GA, Jul 1984.

Goodrich JA. Special tumors of the hand. Bone and Hand Pathology Symposium, Ft Gordon, GA, Jul 1984.

Donovan L. Breast carcinoma. Bone and Hand Pathology Symposium, Ft Gordon, GA, Jul 1984.

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Donovan LT, Smith DS, Warncke RM, Shade RD. Femoral neck stress: The need for prophylactic Knowles pinning. Soc Mil Orthop Surgeons, Colorado Springs, CO, Nov 1983.

Ophthalmology Service

Riffle J. Advances in diabetic retinopathy. 159th Reunion Jefferson Medical College Alumni Assn, Philadelphia, PA, Jun 1984.

RESIDENTIAL TREATMENT FACILITY

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Hester TW. RTF update. Residential Treatment Facility Director's Meeting, El Paso, TX, Feb 1984.

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Mulder LR, Lange G: Implications for nurses. Georgia Nurses' Assn, Columbus, GA, Feb 1984.

Staton DJ: Chemotherapy for oncology patients - nursing care, side effects, problems of administration. Georgia Nurses' Assn, Columbus, GA, Feb 1984.

Rehm A: Role of the clinical nurse specialist in the Army. Phyllis Verhonick Research Course. Washington, DC, Sep 1984.

Thomas L: The knowledge of professional psychiatric personnel regarding the legal rights of clients in public treatment facilities. Georgia Nurses' Assn, Columbus, GA, Sep 1984.

Munn AR: Implementation of the New Center for Disease Control (CDC) Guidelines. Martin Army Community Hospital Jan and Feb 1984; Columbus, GA, Feb 1984.

Staton DJ: Death and dying. Muscogee Manor Nursing Conference. Columbus, GA, Jun 1984.

Staton DJ: Physiological aspects of aging - nursing care of geriatric patients. Muscogee Manor Nursing Conference. Columbus, GA, Jul 1984.

Stanford TW Jr: Periodontist. Alabama Chapter, American College of Dentists, University of Alabama, Jan 1984.

Decker PJ: Meningococcal meningitis. Prev Med NCO Training and Management Conference, Ft Sam Houston, TX, Apr 1984.

Butterfield H: Asbestos. Dept of Engineering and Housing, Ft Benning, GA, Apr 1984.

Aiken AC: Industrial hygiene and occupational health program at Fort Benning. 14th Environmental Engineers and Sanitation Workshop, Fitzsimons Army Medical Center, CO, May 1984.

Decker PJ, Aiken AC: Heat stress. 7th District Environmentalist, Georgia Public Health, Hamilton, GA, Sep 1984.

Wolf P, Saultz J: Teaching neurolinguistic programing skills to medical students. National Meeting Society Teachers of Family Med, Orlando, FL, May 1984.

Saultz J: Why do patients choose a family physician - A preliminary analysis. Family Medicine Annual Faculty Development Fellowship Symposium. University of North Carolina, Chapel Hill, NC, Jun 1984.

Saultz J: Neurolinguistic program: Use in behavioral science education in family medicine. Ann Meeting Family Practice Clerkship Coordinators, Uniformed Services University of Health Sciences, Bethesda, MD, Aug 1984.

Carroll DA: Developing a wellness curriculum for Family Practice Residency Program. Annual Residency Assistance Program Workshop for Faculty and Staff of Family Practice Residencies, Kansas City, MO, Apr 1984.

Detail Summary Sheet

Date: 13 Jun 84 Prot No.: 78-5 Status: Terminated
 Title: A Vascular Occlusion Stroke Model: I. A Technique for Evaluating
 Therapeutic Approach and Predisposing Factors.

Start Date: Feb 78		Est Comp Date:
Principal Investigator(s) Charles J. Hannan, Jr., PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate predisposing factors and experimental therapies in the gerbil model of cerebral ischemic stroke.

Technical Approach: Temporary surgical occlusion of both common carotid arteries for 40 minutes was employed to produce an experimental model of stroke.

Progress: Difficulties in the reliable measurement of superoxide dismutase (SOD) in plasma caused delay of this project. The PCS of the principal investigator prevents further development of this project.

Beckman JS, Hannan CJ. Superoxide dismutase-polyethylene glycol (PEG-SOD) as a free radical scavenger in gerbil cerebral ischemia and reflow. Presented at Soc Neuroscience, Boston, MA, Nov 1983.

Detail Summary Sheet

Date: 2 Oct 84 Prot No.: 79-7 Status: Ongoing
 Title: Control of Gonadotropin Secretion in the Male Rat.

Start Date: May 79		Est Comp Date:
Principal Investigator(s) James C. McPherson III, PhD, DAC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words: Gonadotropins Steroids		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the role of estrogens, progestins and androgens either alone or in combination in the regulation of gonadotropin secretion.

Technical Approach: Immature male and female rats and neonatally androgenized female rats are castrated and given replacement steroid therapy beginning immediately and continuing for five days. These animal models are utilized to study the effects of various steroids both individually and in combination on the control of gonadotropin secretion, including the pituitary sensitivity to LHRH, peptide and neurotransmitter roles. Secondary sex organs are removed and weighed as a measure of biological activity of the steroids. Serum and tissue samples are analyzed for a variety of endocrine components including gonadotropins, peptides, steroids and neurotransmitters.

Progress: Progress on this protocol has been delayed while evaluating sources for radioimmunoassays for peptides, protein hormones and steroids. New materials have now been identified which will allow progress on this study. An addition in animal strain to include Sprague Dawley and Fisher F344 is being made. The Fisher rat is being promoted by the National Institute of Health for use on aging studies. The same animal models will be utilized with this strain to assist in the evaluation of studies involving reproductive physiology.

Detail Summary Sheet

Date: 2 Oct 84 Prot No.: 79-19 Status: Ongoing
 Title: Gastrointestinal Hormones in Non-Ionic Surface Active Agent Induced Delay of Gastric Emptying.

Start Date: Jan 80		Est Comp Date:
Principal Investigator(s) James C. McPherson III, PhD, DAC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators: James C. McPherson, Jr., M.D., Medical College of Georgia
Key Words: Gastric emptying Surfactants Gastric secretion		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the effect of non-ionic surface active agents on gastric emptying, voluntary food consumption, body weight and blood chemistries.

Technical Approach: Groups of fasted rats were given non-ionic surface active agents followed 30 minutes later by a commercial rat tube feeding diet. Animals were sacrificed at various times after feeding and gastric emptying compared to control groups. In another series of experiments, rats were injected daily for four days with non-ionic surface active agents. Voluntary food consumption before and during treatment was measured. Twenty-four hours following the last injection, the animals were sacrificed and blood drawn for blood chemistries. In an additional series of experiments the effect of non-ionic surface active agents on gastric secretion is being assessed. Cimetidine, a known gastric secretion inhibitor and metoclopramide, a known agent that stimulates motility of the upper gastrointestinal tract without stimulating gastric secretion, have been utilized to access the actions of these non-ionic surface active agents on delayed gastric emptying. Serum gastrin levels were assayed by radioimmunoassay in fed and non-fed rats given saline or Triton WR-1339 (a non-ionic surface active agent which delays gastric emptying).

Progress: Earlier studies showed Triton WR-1339, a non-ionic surfactant, to delay gastric emptying, increase gastric secretion and sustain increased levels of gastrin. New studies have shown pluronic polyol F-127, another non-ionic surfactant, to have no effect on gastric emptying, normal gastric secretion but with sustained elevated levels of gastrin. These elevated gastrin levels are associated with increased cholesterol and triglyceride levels. Pluronic F-127 appears to have little if any effect on gastrin release directly since there are no increased levels of serum gastrin during the early time periods when gastrin secretion is stimulated by feeding, in either fed or non-fed animals. Pluronic F-127 appears to maintain high circulating levels

79-19 Continued

of serum gastrin following gastric emptying due to an inhibition of gastrin catabolism.

Presentations and publications:

Apparent increased serum gastrin levels associated with hyperlipemia and normal gastric emptying. 7th International Congress of Endocrinology, Quebec City, Canada, Jul 1984.

Published abstract: Excerpta Medica International Congress Series 652: 7th Intl Congress of Endocrinology. Amsterdam: Elsevier Science, 1984; p 858.

The effect of fasting on the hyperlipemic response to triton WR-1339 and pluronic F-127. Annual Meeting, Georgia Nutrition Council, Atlanta, GA, Mar 1984.

Published abstract: Georgia Nutr Council Ann Conf, Res Sect, Abstr, 1984, p.5.

Detail Summary Sheet

Date: 5 Oct 84 Prot No.: 79-21 Status: Ongoing
 Title: The Experimental Fat Embolism Syndrome: An Electron Microscopic Study of Lung in Three Models.

Start Date: Jun 80		Est Comp Date:
Principal Investigator(s) Jack A. Horner, B.S., DAC		Facility: DDEAMC
Dept/Svc:		Associate Investigators: James C. McPherson III, PhD, DAC James C. McPherson, Jr., M.D., Medical College of Georgia
Clinical Investigation		
Key Words: Fat embolism Electron Microscopy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:\$1200	Periodic Review Results

Study Objective: Experimental fat embolism syndrome is usually induced by one of five techniques: 1) fracture of the femur of an animal, 2) injection of extracted or homogenized adipose tissue from a same species donor, 3) injections of olive oil or purified triolein, 4) injection of oleic acid, or 5) injection of mineral oil (all injections given intravenously). In this study the similarity and differences, if any, in these last three techniques (olive oil, oleic acid, and mineral oil) will be investigated.

Technical Approach: Fat embolism is a major (although frequently undiagnosed unless severe) complication in patients with fractures of the long bones and/or severe trauma. The etiological mechanism of this syndrome is still unsettled. The two mechanisms most widely accepted are: 1) fat from the bone marrow of fractured bones or traumatized adipose tissue enter into small broken veins and travel to the lung where blockage of the capillaries and arterioles occur, and 2) after trauma, the circulating lipoproteins in blood coalesce to form globules of fat large enough to block the capillaries of the lung. In addition, once the fat has blocked a capillary or arteriole, the pathogenic events which follow are unclear. The major effect may be a simple blockage, but some investigators believe the most harmful effects result from the release of free fatty acids from the "trapped" fat globules in the lung. This study will attempt to establish the differences which could be important in the clinical syndrome by examining a mineral oil model (pure blockage with no possible release of free fatty acid from the globules), oleic acid (effect of free fatty acid only), and olive oil (fat capable of hydrolysis to yield free fatty acids). This study may add to our basic understanding of the events in the pathogenesis of the clinical fat embolism syndrome and suggest the basis of new methods of treatment.

Progress: An apparatus to permit the fixation of pulmonary time by osmium tetroxide vapors had been completed. Full resumption of this study was delayed while a new electron microscopy technician was undergoing training. This project has recently been resumed.

Detail Summary Sheet

Date: 5 Oct 84 Prot No.: 79-23 Status: Completed
 Title: Examination of Multi-Microbial Abscesses in Animal Models: II.
 Morphological and Bacteriological Comparison.

Start Date: Oct 82	Est Comp Date:
Principal Investigator(s) Richard W. Harris, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators: Jack A. Horner, DAC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To examine bacteriological and physiological parameters of an animal abscess model involving continuous sampling.

Technical Approach: To examine the morphological definition of abscesses by scanning electron microscopy during the development of the abscess.

Progress: Our initial investigations indicated that the examination of anti-biotic penetration into intra-abdominal infections produced in plastic capsules implanted into rabbits would be a more clinically relevant and productive line of investigation.

Detail Summary Sheet

Date: 5 Oct 84 Prot No.: 80-28 Status: Ongoing
 Title: Antimicrobial Therapy in an Animal Abscess Model.

Start Date: Jun 81		Est Comp Date:
Principal Investigator(s) Richard W. Harris, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation/Medicine		Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To develop an appropriate methodology for examination of effects of antibiotics on monomicrobial and polymicrobial abscesses.

Technical Approach: In order to produce an encapsulated virulent strain, all stock organisms studied will be passed through a mouse or rat by subcutaneous injection with soft agar. The aspirated organism will then be used for rabbit inoculation. Sterile plastic capsules will be implanted intraperitoneally into New Zealand white rabbits. The animals will be kept six weeks and bacteria injected into the capsule prior to initiation of antibiotic therapy. Cost to date: \$5,000.

Progress: The antimicrobial activity of moxalactam was examined against Bacteroides fragilis and Escherichia coli individually and in combination during 10 days of therapy given both at 40 mg/kg/day and 120 mg/kg/day. Although bacterial colony counts were significantly decreased, sterilization of the capsule fluid did not occur.

Harris RW, Moore WL Jr, Arensman JB, Rissing JP: Antimicrobial activity of moxalactam against both B. fragilis and E. coli in an intraperitoneal abscess mode. J Antimicrobial Chemotherapy. (In Press)

Harris RW, Hobbs CF, Buxton TS, et al: Antimicrobial efficacy of moxalactam against a mixed B. fragilis and E. coli intra-abdominal infection in rabbits. Accepted for presentation at 24th ICAAC, Oct 1984.

Detail Summary Sheet

Date: 5 Oct 84 Prot No.: 80-29 Status: Ongoing
 Title: Differentiation of Bacteria in vivo by Gas Liquid Chromatography.

Start Date: Nov 81		Est Comp Date:
Principal Investigator(s) Richard W. Harris, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine patterns of metabolite production by electron capture gas chromatography in an abscess animal model.

Technical Approach: Exudate from the rabbit model will be used to compare monomicrobial abscesses. Organisms will be implanted with soft agar and exudate will be examined upon abscess formation. Serum will be drawn for determination of metabolites.

Progress: This study will not be initiated until present technical personnel are trained in use of gas chromatography equipment.

Detail Summary Sheet

Date: 1 Oct 84 Prot No.: 81-16 Status: Ongoing
 Title: Correlations Between Amount of Information Feedback and Success of Biofeedback Treatments.

Start Date: Feb 81		Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation Psychology Service		Associate Investigators: Anthony Ficara, DDS, COL, DC Roberto Barja, MD, COL, MC Benjamin Hanson, DDS, MAJ, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 83 Review Results Continue

Study Objective: To determine whether increasing the amount of information about muscle tension given to patients with muscular control problems will shorten treatment times and increase the overall effectiveness of the treatment.

Technical Approach: For patients with bruxism, half receive muscle tension feedback from the masseter muscle, weekly in the laboratory, and wear a masseter tension monitor nightly at home. The other half does the same with the addition of receiving feedback from the night monitor when they begin tensing their jaws. For patients with subluxation of the patella, muscle tension in the vastus medialis and lateralis will be recorded. Half will receive a combined feedback proportional to their relative tension and half will receive two independent signals juxtaposed in various ways indicating both relative and absolute muscle tension.

Number of subjects enrolled to date: 131

Number of subjects enrolled for reporting period: 38

Progress: To date this study has established that 1) biofeedback from the masseter is only useful in the treatment of jaw area pain if the muscles are abnormally tense, and 2) there is no relationship between results of the MMPI and treatment success. These are important findings because previous studies of this prevalent, difficult problem have not differentiated between pain due to joint problems alone, muscle and joint problems, and muscle alone. These studies had very mixed results. Our study shows that much of the variability is probably due to the failure to differentiate between varied underlying causes of the pain. In the past, those TMJ patients who produced abnormal patterns on the test's first three scales were considered to be treatable only through psychiatric intervention. This attitude spread to such an extent that the large body of anecdotal literature indicates that most, if not all, bruxism patients have significant psychiatric concomitants of their disorder. Our study is the first to begin questioning this assumption in an objective way. We have begun a second phase of the project in which patients are

Detail Summary Sheet

Date: 26 Sep 84 Prot No.: 81-17 Status: Terminated
 Title: Intrasection Psychophysiologic Arousal Correlates of Psychotherapy and Behavior Treatment.

Start Date: Feb 81	Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation, Psychiatry / Neuro	Associate Investigators: Ralph Bruno, PhD, CPT, MSC William G. Bissell, M.D., LTC, MC
Key Words: Arousal Psychotherapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Mar 83 Review Results Continue

Study Objective: To monitor patterns of arousal among patients undergoing group psychotherapy, individual psychotherapy, or individual behavior therapy to detect correlations between therapeutic work/intervention and arousal (as reflected by psychophysiologic parameters) during a session.

Technical Approach: Patients in the above settings will be instrumented appropriately so that various psychophysiologic parameters indicative of arousal (heart rate, respiration rate, number of GSR's, muscle tension, peripheral vasoconstriction, etc.) can be continuously monitored throughout a session. All verbal interactions will be recorded on a second by second basis on the physiologic data tape to permit correlation between arousal and therapy.

No patients were enrolled.

Progress: Study terminated due to ETS of co-investigators and lack of availability of a technician to carry out the project.

Detail Summary Sheet

Date: 1 Oct 84 Prot No.: 81-18 Status: Ongoing
 Title: Environmental Stress and Electromyographic Correlates of Chronic
 Posterior Trunk Muscle Pain.

Start Date: Feb 81		Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation Psychology, Orthopedics		Associate Investigators: Roberto Barja, MD, COL, MC
Key Words: Low back pain Upper back pain Muscle tension		
Accumulative MEDCASE Cost: \$19,000	Est Accumulative OMA Cost:	Periodic Mar 84 Review Results Continue

Study Objective: To record those muscles in the posterior trunk of patients with lower and upper back, shoulder, or neck pain related to abnormal muscle tension in order to ascertain relationships between stress, pain, and tension as well as evaluate the effectiveness of muscular relaxation training as a treatment for these problems. The relative effectiveness of these treatments for pain in the above areas with and without underlying muscle tension problems will be evaluated.

Technical Approach: Recordings of muscle tension; objective psychosomatic measures of stress, anxiety, functional locus and other factors; discomfort logs; and other measures will be made before, during and after muscle relaxation treatments of individuals with the problems described above. These progressive measures will be compared with identical measures made of individuals with: 1) musculoskeletal related pain in other areas; 2) high anxiety but no musculoskeletal pain; and 3) posterior trunk pain but no muscle tension problem. A second phase of the study will consist of continuous muscle tension recordings made throughout the day using wearable EMG recorders. These measures will be related to a continuously tape recorded log of environmental loci and stresses.

Number of subjects enrolled to date: 227

Number of subjects enrolled for reporting period: 114

Progress: To date this study has demonstrated that 83 patients with low back pain diagnosed as being due to muscle spasm/tension have highly individualized patterns of muscle tension. When the paraspinal muscles are recorded while the patient is standing, prone, bending, or sitting supported or unsupported only one or two show abnormally elevated levels. These patterns remain stable across up to six recording sessions as long as the pain level remains constant. There is a high positive correlation between level of tension in the most abnormal position and reported intensity of pain. This relationship

did not hold for 31 muscle contraction headache controls. This finding explains why the literature on low back muscle tension is so inconsistent. No previous works took pain level into account or recordings in multiple positions. The data would appear random if the study was restricted to one position and without regard to pain level because different people are abnormal in only a few positions.

These results were presented at the Society of Military Orthopedic Surgeons and the International Association for the Study of Pain meetings.

We are currently extending the study to include more diagnoses and to evaluate the effects of the position subjects find most uncomfortable. We are also using videothermographic recordings in addition to surface EMG in order to objectively evaluate the nerve pinch and muscle irritation components of low back pain.

We are simultaneously beginning the second phase of the project. In this phase, environmental recordings of paraspinal EMG are made throughout the subject's waking hours and are correlated with hourly reports of pain and activity. The recording device has now been entirely designed and is under construction.

The study has been extended to evaluate the accuracy of the results of the Minnesota Multiphasic Personality Inventory (MMPI) when used with chronic low back pain patients. In the past, abnormal elevations of clinical scales one and three (the infamous conversion "V") were interpreted as indicating that the pain was exacerbated significantly by psychological factors. This led many physicians to conclude that their patients were "psychosomatic" and, thus, could not be treated physically. However, the MMPI was normalized using pain free patients. Many of the questions which are incorporated into scales one and three concern physical problems which frequently occur among chronic low back pain patients such as inability to sit still for long periods, broken sleep, etc.

We are having 200 sequentially selected chronic low back pain patients at DDEAMC and a further 100 at the Augusta VAMC answer the questions from these scales as they would both with and without pain. If the "V" is present for the pain state answers, but not for the pain-free state answers, it is an artefact.

Detail Summary Sheet

Date: 2 Oct 84 Prot No.: 81-19 Status: Ongoing
 Title: Investigations of Chronic Phantom Pain.

Start Date: Feb 81		Est Comp Date: Jan 85
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc:		Associate Investigators: Norman Gall, M.D., AMVAH San Antonio
Clinical Investigation		Roberto H. Barja, M.D., COL, MC
Key Words: Phantom pain		Jeff Ernst, PhD, VA, Augusta
Accumulative MEDCASE Cost:\$18,000	Est Accumulative OMA Cost: \$900	Periodic Mar 84 Review Results Continue

Study Objective: 1) Develop an understanding of the underlying causes of phantom pain; 2) determine the extent of phantom pain among the amputee population; 3) develop comparative differential profiles of amputees with and without phantom pain; and 4) evaluate new treatments of phantom pain.

Technical Approach: All service connected amputees who can be located receive a mail survey requesting information about their amputation, stump pain, phantom pain, etc. All service connected veterans living near DDEAMC and all amputees treated at DDEAMC or VAMC Augusta are asked to participate in a psychometric and psychophysiologic profile. All phantom pain patients seen at any participating center receive the same profile as part of the pretreatment workup.

Progress: Since the last report we have added a very sensitive videothermography system to our array of physiological recorded devices. We have used it to demonstrate the physiological basis for any etiological type of phantom limb pain. This is the first time a physical basis for any type of phantom pain has been observed. We have a series of patients reporting during phantom limb pain for whom there is a high negative correlation between blood flow at the distal end of the stump and intensity of phantom limb pain.

This work has been published in Orthopedics, 1984; 7(8):1319-1320; and reported at various meetings, e.g., International Association for Study of Pain and the Disabled American Veterans.

Our work on prevalence and characteristics of phantom limb pain has been completed with the publication of our work on a comparison of civilian and military related amputees in Pain Vol 19, 1985. The work on over 7,000 military amputees was also published recently in Pain 1984; 18:83-95; and Am J Physical Med 1984; 62:227-238.

The study of phantom pain has been extended to include phantom body pain. To date, we have evaluated the blood flow and muscle tension correlates of 14

patients with clinical diagnoses of complete transections of the spinal cord. All reported clearly delineated painful sensations below the level of normal sensation. All showed relatively warm areas exactly correlating with painful sites. This was true for both large areas and randomly dispersed dime size irregularly shaped spots. There does not appear to be an relationship between sympathetic or CNS dermatomes or blood supply systems and the warm/painful areas, so that reflex responses are not likely to be an underlying cause of the altered blood flow. This work has been prepared for publication. We intend to continue this work and to survey spinal cord injured veterans in similar ways to the surveyed veteran amputees. This will provide information on incidence and severity of phantom body pain as well as on problems and requirements for treatment. We have asked the Paralyzed Veterans of America to support a technician to aid us in carrying out the project.

We have begun our investigation of physiological and environmental correlates of phantom limb pain. This will be accomplished through a combination of home logs kept by 1,000 amputees and laboratory recordings of 100. The Veterans Administration is supplying a technician to support this three-year effort. If the results lead to demonstration of specific mechanisms, functional treatments can be developed. We have shown that at this time there are NO effective treatments for most types of phantom limb pain. We are continuing to test our treatments for spasmodic and burning phantom pain.

Detail Summary Sheet

Date: 2 Oct 84		Prot No.: 81-42		Status: Ongoing	
Title: Experimental Fat Embolism Syndrome: Basic Studies and Evaluation of Currently Available Therapies and New Agents.					
Start Date: Oct 81			Est Comp Date:		
Principal Investigator(s) James C. McPherson III, PhD, DAC			Facility: DDEAMC		
Dept/Svc: Clinical Investigation			Associate Investigators: Jack A. Horner, DAC J. Bruce Arensman, DVM, MAJ, VC Robert Prior, DAC		
Key Words: Fat embolism Surfactants					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: Evaluation of current therapies and new therapies for treatment of fat embolism syndrome in an experimental animal model.

Technical Approach: This project is being investigated in five phases. Metabolic evaluation of the non-ionic surface active agents is being conducted using an eleven parameter profile developed to screen these agents and analyzed by a Technicon RA-1000 (a mini-SMA instrument). The profile includes cholesterol, triglyceride, glucose, urea N, creatinine, uric acid, bilirubin, LDH, SGOT, CPK and ALT. Electrolyte blood cell indices and other parameters are under investigation or consideration.

Progress: A number of advances have been made on this protocol this year. The tetronic polyol series of surfactants have been evaluated as to their ability to produce endogenous hyperlipemia. These agents appear to be alternative agents to replace Triton WR-1339 in studies to evaluate hypolipemic drugs. Additional drug studies determined the rate of lipoprotein secretion and the effect of fasting on the hyperlipemic response. Fasting markedly suppresses the hyperlipemic response to these drugs and immediate refeeding rapidly affects this response in Pluronic F-127 induced hyperlipemia. Additional studies have been developed this year due to observations during other experiments. Effects of these drugs on osmotic fragility, hematocrit, surface tension and viscosity of whole blood and blood constituents have begun. Observations include reduced surface tension of washed red blood cells as compared to plasma or whole blood, changes in surface tension of whole blood with various drugs and the development of a very sensitive test for hemoglobin to assist in determining the hemolysis of red blood cells by various agents. Changes in surface tension and blood viscosity by these drugs may play an important role in improving the microcirculation of compromised patients.

Presentations and publications listed on next page.

81-42 Continued

Presentations and publications:

Pharmacodynamic effects of intravenous pluronic polyols F-38, F-68, F-77, F-88, F-108, F-127 and P-105: Effects on serum lipids and other constituents. Soc Experi Biol Med, Southeastern Section, Medical College of Virginia, Richmond, VA, Nov 1983.

Published abstract: Soc Experi Biol Med, SE Section, 1983; 8(26):16.

Endogenous hyperlipemia from non-ionic surface active agents (NISAA) of the tetronic polyol series. 68th Annual Meeting, Federation of American Societies for Experimental Biology, St Louis, MO, Apr 1984.

Published abstract: Federation Proc, 1984; 562:562.

Pharmacologic responses to some newer hyperlipemic agents (pluronic polyols). 18th Annual Regional Lipid Conference, Cashiers, NC, Nov 1983.

The effect of various non-ionic surface active agents on surface tension measurements of blood constituents. 61st Annual Meeting, Georgia Academy of Science, Statesboro, GA, May 1984.

Published abstract: GA J Sci, 1984; 42(1-2):26.

Hemolytic activity of Triton WR-1339 (TWR), a non-ionic surface active agent, in vivo. 61st Annual Meeting, Georgia Academy of Science, Statesboro, GA, May 1984.

Published abstract: GA J Sci, 1984; 42(1-2):26-27.

The effect of various non-ionic surface active agents on viscosity of whole blood. 61st Annual Meeting, Georgia Academy of Science, Statesboro, GA, May 1984.

Published abstract: GA J Sci, 1984; 42(1-2):26.

Surface tension of various non-ionic surface active agents in whole blood. 61st Annual Meeting, Georgia Academy of Science, Statesboro, GA, May 1984.

Published abstract: GA J Sci, 1984; 42(1-2):26.

Effect of buffering on osmotic fragility and hematocrit of RBC's. 61st Annual Meeting, Georgia Academy of Science, Statesboro, GA, May 1984.

Published abstract: GA J Sci, 1984; 42(1-2):45.

Detail Summary Sheet

Date: 2 Oct 84 Prot No.: 82-20 Status: Ongoing
 Title: Correlations Between Extent of Patient Involvement and Effectiveness
 of Published Behavioral Treatments of Hypertension.

Start Date: Nov 81		Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words: Patient involvement Hypertension Behavioral treatment		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
		Periodic Review Results

Study Objective: To determine whether the extent of patient in behavioral treatment of hypertension affects treatment success.

Technical Approach: The methods and results sections of all published articles on behavioral treatment of hypertension containing sufficient detail to permit analysis are sorted into "blind" booklets for rating. Physician and PhD groups are asked to "blind" rate each method and result section without knowing which are related to each other.

Progress: All data has been gathered but analysis is not yet complete due to the lack of statistical support.

Detail Summary Sheet

Date: 2 Oct 84 Prot No.: 82-43 Status: Ongoing
 Title: Development of an Animal Model of Phantom Pain.

Start Date:		Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators: Mrs. Crystal Sherman, M.S.
Key Words: Phantom pain Animal model Rat		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$3,200	Periodic Review Results
Study Objective: To develop an animal model of phantom pain.		

Technical Approach: Rats are trained to respond to gentle, harmless, shocks by pressing different levers depending on where along the foreleg the shock is given in order to receive a milk reward. After training is successful, the foreleg is amputated by a combined veterinary-orthopedic surgery team while the animal is under anesthesia. Following recovery, the shocks are presented to the remaining portion of the foreleg. The number of responses to stimulation of areas no longer present are compared with the previous number of incorrect responses.

Progress: Study not yet started due to the lack of a technician. The technician has been selected and is due to start in late October 1984. The project should begin shortly thereafter.

Detail Summary Sheet

Date: 13 Jun 84 Prot No.: 82-44 Status: Completed
 Title: Biochemistry of Acute Psychosis.

Start Date: Jun 82	Est Comp Date:
Principal Investigator(s) Charles J. Hannan, Jr., PhD, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation, Psychiatry	Associate Investigators: William F. Shivers, Jr, M.D., LTC, MC G. Franklin Carl, PhD, VAMC Alan Boulton, DSc, Univ Hospital Saskatoon, Canada
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Jul 84 Review Results Completed

Study Objective: Through a multicenter cooperative effort, biochemical measurements will be made on blood fractions obtained from DDEAMC psychiatric patients, and these results will be correlated with symptomatology.

Technical Approach: Study design will be composed of four parts: a) psychiatric diagnostic criteria and coordination of referral sources for inclusion of subjects and controls; b) collection, fractionation and distribution of blood products to investigators; c) biochemical determination on blood fractions by investigators; d) collection and analysis of data considering diagnostic information and two month followup of subjects.

Number of subjects enrolled to date: 35

Number of subjects enrolled for reporting period: 0.

Progress: Most of the data for this study is completed, lacking only the biochemical measures for 12 subjects, which are being performed by Dr. Boulton. Data analysis of results is now being planned with correlative and clustering methods. Results are expected to be published.

Hannan CJ, Shivers WF. Effect of 8-phenylethylamine on regional brain catechol-o-methyl-transferase activity. Presented at Soc Neuro Sci, Boston, MA, Nov 1983.

Detail Summary Sheet

Date: 2 Oct 84 Prot No.: 83-8 Status: Ongoing
 Title: Effects of the Psychophysiologic Recording Environment on Stress
 Labile Physiologic Systems.

Start Date:	Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators: Jack A. Horner, B.S., DAC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: 1) To determine the placebo value of an electronic device used with several physiologic dysfunctions in which stress is the major independent variable underlying temporal patterns of severity. 2) To evaluate habituation to the environment through repeated recording of the parameters over time.

Technical Approach: Forty, newly diagnosed, unmedicated borderline hypertensives (BPs in range of 140/90 - 160/110) and 40 chronic tension headache patients will participate in the study. All participants will be basically free of other disorders at the start of the study and will be dropped from the study if need for medication occurs, or other problems develop.

Progress: Study not yet started due to lack of a technician. The technician has been selected and is due to start in October 1984. The project should begin shortly thereafter.

Detail Summary Sheet

Date 14 Jun 84	Prot No.: 83-34	Status: Terminated
Title: Visualization of Imipramine Binding Sites on Red Blood Cells and Platelets.		
Start Date:	Est Comp Date: Jul 84	
Principal Investigator(s) Charles J. Hannan, Jr., PhD, CPT, MSC Jack A. Horner, DAC	Facility: DDEAMC	
Dept/Svc: Clinical Investigation	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jul 84 Review Results Terminate

Study Objective: Imipramine binding is known to correlate with serotonin uptake in platelets. Serotonin uptake, and therefore, imipramine binding, have been demonstrated to be abnormal in various psychiatric diseases. Our goal is to visualize these binding sites using a radioactive tracer to expose fine photographic emulsion and view their spatial arrangement under the scanning electron microscope (SEM).

Technical Approach: This study will be conducted in two parts. Part one will involve the perfection of the SEM autoradiographic techniques using human blood obtained as excess from the blood bank. Part two will involve the application of these techniques to a patient population. The patients utilized will be those already consenting to participate in DDEAMC Protocol 82-44 "Biochemistry of Acute Psychosis." No additional blood will be drawn since that presently obtained under the protocol is sufficient in quantity to supply the few drops needed for this further test. Protocol 82-44 includes a suitable control population which will also serve for this study.

The techniques to be established in part one will basically be modified from the work of Weiss (1980). The primary concern will be to determine a processing regimen which does not remove the bound (^3H)-imipramine until after the autoradiogram is exposed. The general scheme will entail incubation of the RBC's and/or platelets with (^3H)-imipramine, attachment of the cells/platelets to glass cover slips, fixation in glutaraldehyde and osmium tetroxide, deposition of Ilford L-4 Nuclear Track Emulsion, exposure, development, photographic fixation, dehydration, critical point drying and subsequent examination in the scanning electron microscope.

Progress: This study was not implemented due to the PCS of the principal investigator.

Detail Summary Sheet

Date: 4 Oct 84		Prot No.: 84-5		Status: Ongoing	
Title: Chronic Osteomyelitis Animal Model With <u>Staphylococcus aureus</u> and <u>Bacteroides fragilis</u> .					
Start Date: Nov 83			Est Comp Date:		
Principal Investigator(s)			Facility:		
Richard W. Harris, CPT, MSC			DDEAMC and VAMC Augusta		
Dept/Svc:			Associate Investigators:		
Clinical Investigation					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To develop a model of chronic osteomyelitis using S. aureus and B. fragilis and to study the pathology of the disease and treatment.

Technical Approach: Rat tibiae were aseptically exposed under an anesthesia, a small hole was drilled in the bone and injected with 5 µl of either Bacteroides fragilis, staphylococcus aureus or both organisms, and the wound closed with bone wax. Animals were maintained up to 70 days and evaluated for gross, pathology, bacterial colony counts and percent of bone involvement.

Progress: An S. aureus inoculation (65/5 µl log 10 cfu) of rat tibiae produced an infection at 35 days with a bacteria population of approximately 4 log 10 cfu/gm bone. Animals receiving S. aureus plus B. fragilis had an increase in S. aureus colony counts 5.6 log 10 cfu/gm bone and half the rats (7 of 13) demonstrated more severe gross pathology than the rats inoculated with S. aureus alone. This model did not require the use of a sclerosing agent (sodium morrhuate) to produce infection. Animals sacrificed after 70 days contained similar infection to the day 35 animals. Protocol is being done by personnel at the VA Infectious Disease Lab and the Department of Clinical Investigation Microbiology Service.

Rissing JP, Buxton TB, Harris RW, Shockley RK: Experimental staphylococcal osteomyelitis in rats. Augmentation of pathology by B. fragilis and arachidonic acid. Clin Res 1983; 31(5):881.

Rissing JP, Buxton TB, Harris RW, Shockley RK: Experimental S. aureus osteomyelitis in rats: Effects of arachidonic acid and B. fragilis. American Federation for Clinical Research 1984. (Accepted for abstract publication)

Rissing JP, Buxton TB, Harris RW, Shockley RK: Bimicrobial experimental S. aureus osteomyelitis in rats: Facilitation of infection by B. fragilis. Accepted for presentation at 24th ICAAC, October 1984.

Detail Summary Sheet

Date: 5 Oct 84 Prot No.: 83-37 Status: Ongoing
 Title: Determination of Glomerular and Nonglomerular Bleeding by Examination of RBC's in Urine Using Scanning Electron Microscope (SEM).

Start Date: Jul 83	Est Comp Date: Mar 85
Principal Investigator(s) Jack A. Horner, DAC James A. Hasbargen, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators:
Key Words: Electron microscopy, Kidney biopsy, Glomerular bleeding	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Review Results

Study Objective: It has recently been suggested that red blood cells (RBC) from glomerular causes appear different than RBC from nonglomerular causes. Our goal is twofold: a) to insure the differences are not secondary to osmotic or fixation artifacts, and b) to quantitate and confirm the prior observations.

Technical Approach: This study consists of two parts, a study of urine bound red blood cell (RBC) morphological changes as a result of urine parameters (e.g., holding time, pH, osmolarity, etc.), and a characterization of RBC morphology in urine from patients with hematuria both with and without glomerular bleeding. In the first part, normal peripheral blood is placed in urines of varying pH, osmolarity, etc for varying times. The samples are then spun down, fixed in glutaraldehyde, dehydrated, filtered onto nucleopore 0.2µ filters, critical point dried, gold sputtered, and examined in the scanning electron microscope. A minimum of 100 RBC's from each sample will be examined, then morphology noted, and representative cells photographed to determine the effect of urine parameters on RBC morphology. In the second part the same processing regimen is employed on patient urine samples and the resultant RBC morphology recorded.

Progress: Evaluation of artefacts introduced by widely varying pH's and osmolarities of urine were completed. The unique "torroidial" morphology of the glomerular bleeding RBC's could not be synthesized. The effect of prolonged holding times was also shown to be negative. A total of four confirmed cases of glomerular bleeding (confirmed by kidney biopsies) were perfectly correlated with the observed morphology. Seven suspected cases of glomerular bleeding were shown to be negative by the SEM method; all seven were eventually confirmed to be negative by kidney biopsies.

Detail Summary Sheet

Date: 4 Oct 84 Prot No.: 84-6 Status: Completed
 Title: An in vitro Investigation of Bacterial Growth Inhibition by Ca(OH)₂.

Start Date: Nov 83		Est Comp Date:
Principal Investigator(s) Richard W. Harris, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the antimicrobial efficacy of Ca(OH)₂ solution as an irrigant used in endodontics against commonly isolated organisms from root canals comparing to a highly effective antimicrobial irrigant.

Technical Approach: Both facultative and strict anaerobic bacteria routinely found in the oral cavity were evaluated for inhibition by a 100 mM Ca(OH)₂ suspension compared to chlorox, Ca(OH)₂ paste and saline in vitro. Inhibition was determined by zones of inhibition in wells cut out of agar plates, rotation of test solution on a plate with the organisms, and growth in tubes with organisms, test solutions and growth media.

Progress: No inhibition of growth was observed for any group of organisms by Ca(OH)₂ solution, paste or saline. Complete inhibition of growth was observed by chlorox. Results are presently being reviewed for manuscript submission.

Detail Summary Sheet

Date: 5 Oct 84		Prot No.: 84-50		Status: Ongoing	
Title: A Scanning and Transmission Electron Microscopic Study of the Effects of Cadmium on the Early Developmental Components of the Craniofacial Region of the Hamster Embryo					
Start Date: Jul 84			Est Comp Date: Fall 85		
Principal Investigator(s) Jack A. Horner, B.S. Thomas F. Gale, PhD			Facility: DDEAMC Medical College of Georgia		
Dept/Svc: Clinical Investigation Anatomy Dept, MCG			Associate Investigators:		
Key Words: Electron microscopy, Cadmium, Teratology					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To utilize both scanning and transmission electron microscopy to compare the ultrastructural features of the component tissues of the frontonasal, medial and lateral nasal, maxillary, and mandibular prominences at five different times during the period of early development of the craniofacial region in cadmium-treated vs control hamster embryos. To detect the presence of site(s) of intracellular localization of cadmium in the cells of the prominences of the early developing craniofacial region during the same time period by utilizing the technique of energy dispersive analysis of x-rays at the electron microscopic level of resolution.

Technical Approach: Cadmium sulfate solution is injected (IV) into pregnant golden hamsters on discrete gestation days and the embryos are harvested on succeeding days. The embryos are fixed, dehydrated by critical point drying, coated and examined in the scanning electron microscope. Comparisons with normal controls (sham injected) will reveal the teratologic effects of the cadmium. The comparison will be aided by a computer interfaced morphometric digitometer. Representative embryos will also be analyzed using energy dispersive x-ray spectrometry to determine the intracellular localization characteristics of the cadmium.

Progress: Seventy-two animals have been processed to date. The initial results were employed to determine the most appropriate sub-lethal, yet teratologic dosage of cadmium and the most susceptible point of the gestation period. It has been determined that a dosage of 2 mg/kg body weight is most effective, and that early on the 10th gestation day is a period of high susceptibility. Preliminary analysis of the morphometric data indicates a significant teratologic effect which will be quantitated and characterized as the study progresses.

Detail Summary Sheet

Date: 2 Oct 84 Prot No.: 83-32 Status: Ongoing
 Title: Mandibular Lingual Vertical Releasing Incisions.

Start Date: Aug 83		Est Comp Date: May 84
Principal Investigator(s) William M. Ekvall, MAJ, DC		Facility: DDEAMC
Dept/Svc: Dental Activity		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Compare the healing and post-operative sequelae of two different types of incisions used in periodontal surgery.

Technical Approach: Each patient in the study will have each of the two types of incisions performed in his mouth, one on each side of the mandible. Progress of healing will be followed with a symptom data log and clinical photographs.

Number of subjects enrolled to date: 4
 Number of subjects enrolled for reporting period: 3

No adverse complications have occurred.

Progress: Two patients are currently awaiting initiation of their surgeries.

Detail Summary Sheet

Date: 5 Oct 84		Prot No.: 84-8		Status: Completed	
Title: Masseter Muscle Silent Period in Patients With Internal Derangements of the Temporomandibular Joint Before and After Splint Therapy.					
Start Date: Jan 84			Est Comp Date:		
Principal Investigator(s) Benjamin S. Hanson, MAJ, DC			Facility: DDEAMC		
Dept/Svc: Dentistry			Associate Investigators: Anthony J. Ficara, LTC, DC Richard A. Sherman, CPT, MSC		
Key Words: Splints, Silent Period					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the efficacy of splint therapy in temporomandibular joint dysfunction patients.

Technical Approach: At each recording session the subjects were requested to grade the severity of their pain on a 1 to 10 intensity scale, with ten signifying excruciating discomfort. At the initial session an Inframetric 520 video thermograph, capable of resolving heat differences of .1^o C and sensitive to heat created by blood flow patterns at least one centimeter deep was used for visualization of the left and right preauricular region of each individual. Patients were then seated in a chair with optimal head support. EMG recordings were then made of the masseter muscle in relaxed, normal, and tensed position. The jaw jerk reflex was then elicited and recorded. The patients in group 3 had recording made with and without an anterior repositioning splint at the initial and final recording session. Individuals in group 1 had these recordings made only once. Patients in group 2 had data collected initially and three months later, these patients received no treatment for the three month duration of the study. Patients in group 3 had recordings made at the start of treatment, which consisted of continuous therapy with an anterior repositioning splint, and at one month intervals for three months.

Beckman 16 mm surface silver/silver chloride biopotential electrodes with Lector II paste were taped over the masseter muscle of the symptomatic side after the skin had been vigorously scrubbed with an alcohol swab. An ear clip electrode served as the ground, and resistance between all combinations were limited to 100k ohms. The signal was amplified by Coulbourn S -7501 high gain amplifier with the lower and upper cut off frequencies at 32 Hz and 11 Hz respectively, to reduce motion artifact. The gain control was set at 500 mv with a sweep speed of 2 mil sec per division. The oscilloscope beam was triggered to sweep at the instant the reflex hammer made contact with the chin. The raw signal was monitored by a tectronix oscilloscope and recorded photographically and registered on a Honeywell 5600 recorder for analysis. To elicit the silent period the patient was positioned in a chair with his back erect and his head supported. The silent period was then induced by a light tap on the mandibular symphysis with a reflex hammer during a sustained contraction of the masseter muscle with the subjects clenching their teeth in maximal intercuspal position, or in the position dictated by the anterior repositioning splint, this procedure was repeated at least twice.

84-8 Continued

Number of subjects enrolled for reporting period: 34
Adverse reactions: None

Progress: The study population consisted of 34 adults, 15 females and 19 males in good general health. Their ages ranged from 18 to 71 years with a mean age of 34 years. Fifteen of these individuals had a negative history of pain in the temporomandibular joint (TMJ), and clinical examination failed to reveal any symptoms of dysfunction, such as pain on palpation, crepitus, or limitation on opening (group 1). The other 19 individuals were randomly selected from patients accepted for treatment in the TMJ Clinic at Fort Gordon, and assigned to the control group (group 2) or the experimental group (group 3). Only patients with clinical evidence of internal derangement were recruited into groups 2 and 3. All patients signed informed consent forms.

Analysis is not yet complete, but it appears that several conclusions may be drawn: 1) there was no correlation between the degree of clinical success and the duration of the silent period, 2) there was a correlation with the length of the silent period and the patient's pain level, 3) splint therapy was effective in patient suffering from internal derangement of the temporomandibular joint, 4) thermograms were of no diagnostic aid.

Detail Summary Sheet

Date: 10 Oct 84		Prot No.: 84-9		Status: Ongoing	
Title: The Role of Excessive Sympathetic Stimulation on Penicillin Blood Levels After P.O. Administration					
Start Date: Jan 84			Est Comp Date:		
Principal Investigator(s) Rodrigo L. Uribe, MAJ, DC			Facility: DDEAMC		
Dept/Svc: Dentistry-Clinical Investigation			Associate Investigators: Lavelle Ford, MAJ, DC Richard W. Harris, CPT, MSC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the effects, if any, of nervousness and apprehension on the absorption and subsequent blood levels of antibiotics given by mouth. Many patients have heart defects or conditions that require that they receive antibiotics before they undergo dental procedures or other surgical therapy. These antibiotics can be given orally. This study will attempt to determine if nervousness affects the rate at which these antibiotics enter the blood stream.

Technical Approach: Healthy volunteers who have twice previously been given penicillin and are negative by allergy skin test will be chosen for the study. Two grams of penicillin-V will be taken orally the morning of surgery and a peripheral line with a heparin lock started. Samples are taken at time 0, 30 minutes, 60 minutes, 90 minutes, and 120 minutes after closing. One 5 ml sample for a red-topped tube will be drawn for an EDTA tube. Serum will be analyzed by bioassay for penicillin concentration. Plasma will be evaluated by HPLC for catecholamine levels and by RIA for ACTH concentrations. All patients will fill out a self-evaluation stress questionnaire prior to surgery.

Number of patients enrolled to date: 13
Funding to date: approximately \$300

Progress: Thirteen patients have been processed and penicillin concentrations have been obtained. Plasma has been frozen for later processing for catecholamines and ACTH. The patient penicillin concentration means are as follows: 30 min, 13.6 ± 3.0 mg/ml; 60 min, 22.3 ± 3.1 mg/ml; 90 min, 14.5 ± 1.8 mg/ml; and 120 min, 9.5 ± 1.2 mg/ml. Controls are presently being acquired to compare to subjects. Control subjects will be obtained voluntarily and undergo the same sampling procedure. Controls and patient serum penicillin concentrations, ACTH, and catecholamine concentrations and self-evaluation questionnaires will be compared and evaluated. Currently, the biochemistry and microbiology clinical investigation services are supporting the oral surgeons in analyzing the blood.

Detail Summary Sheet

Date: 4 Oct 84 Prot No.: 84-44 Status: Ongoing
 Title: Healing Following Temporomandibular Joint Meniscus Surgery in Rabbits.

Start Date: Sep 84		Est Comp Date: May 85
Principal Investigator(s) William P. Mills, Jr., MAJ, DC		Facility: DDEAMC
Dept/Svc: Dental Activity Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To examine the histological patterns of healing following meniscus plication surgery with and without fascial/dermal grafting of the joint meniscus in the adult rabbit.

Technical Approach: The deep fascia will be incised over the joint, a meniscus plication will be performed. After irrigation, the capsule and subcutaneous tissues will be closed with sutures and the overlying soft tissues approximated with wound clips. Identical procedures will be carried out on the opposite side except fascial/dermal grafts will be placed overlying 2mm surgical defects created in the posterolateral aspect of the disk. Ten white laboratory rabbits will be required.

Progress: Thus far two rabbits have been sacrificed and temporomandibular joints bilaterally have been surgically excised for examination as controls. Eight more experimental animals are to be used, and the first two animals are to receive their meniscus plication surgery on 12 Oct 84.

Detail Summary Sheet

Date 30 Sep 84	Prot No.: 82-53	Status: Terminated
Title: Hospital Hypertension Study Lopressor ^R (Metoprolol Tartrate) Diuretic/ Beta-Blocker Therapy-Protocol 20.		
Start Date: Nov 82	Est Comp Date:	
Principal Investigator(s) Jeannette E. South-Paul, M.D., CPT, MC	Facility: DDEAMC	
Dept/Svc: Family Practice	Associate Investigators: Family Practice Staff	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the efficacy and tolerability of Lopressor^R (Metoprolol tartrate) when used in combination with a diuretic in the treatment of hypertension.

Technical Approach: Patient selection includes outpatients of either sex with a sitting diastolic blood pressure of 95 to 114 mmHg (inclusive). Patients may be untreated hypertensives or previously treated who have not been on antihypertensives for at least two weeks before entering study. No patient will have antihypertensives discontinued for the purpose of being included in the study. Patients with sinus bradycardia, heart block greater than first degree, cardiogenic shock, or overt heart failure should be excluded from the selection. All patients must be treated in strict conformity with the attached package inserts.

Progress: Two subjects enrolled. Unable to enroll suitable numbers, terminate.

Detail Summary Sheet

Date: 19 Oct 84 Prot No.: 82-56 Status: Completed
 Title: Sexual Education Inventory.

Start Date: Oct 82		Est Comp Date:
Principal Investigator(s) Gary N. Matteson, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Family Practice	Associate Investigators: Robert Armstrong, M.D., CPT(P), MC Michael Kimes, M.D., MAJ, MC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To develop a tool to measure the adequacy of a physician's education in the area of sexual problems.

Technical Approach: 1) To develop a questionnaire to determine what education background physicians have in sexual education; 2) determine the prevalence of sexual dysfunctions seen in a Family Practice Clinic; 3) to study the ways physicians deal with patients with sexual dysfunction; 4) to correlate the educational background of the physicians as ascertained on the questionnaire with the reported prevalence of sexual dysfunction seen by the physician.

Progress: Study completed. Article accepted for and now pending publication in the Journal of Family Practice.

Detail Summary Sheet

Date: 4 Oct 84 Prot No.: 83-7 Status: Completed
 Title: Behavioral Science in Military Family Practice Programs: What Do Patients Feel is Relevant?

Start Date: Dec 82	Est Comp Date:
Principal Investigator(s) Robert D. Armstrong, M.D., CPT, MC	Facility: DDEAMC
Dept/Svc: Family Practice	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To determine how much involvement in common psychosocial problems patients of DDEAMC Family Practice Clinic desire of their family doctors. To investigate some variables associated with patient's desire for physician involvement.

Technical Approach: An anonymous questionnaire consisting of approximately 70 items will be distributed to patients in the Family Practice Clinic. Boxes will be located in several prominent places in the clinic for patients to return the completed forms.

Progress: Questionnaires were distributed, collected and preliminary data analysis accomplished and results compared to other similar studies. Army patients appear to desire a much higher level of involvement in psychosocial problems than do those who participated in similar civilian studies. This information was presented at a USAFP meeting in April 1983.

Armstrong R. What do military patients want from the family doctor. Presented at Uniformed Services Academy Family Practice, Washington, DC, April 1983.

Detail Summary Sheet

Date: 17 Oct 84 Prot No.: 83-36 Status: Ongoing
 Title: The Interrelationship of Pregnancy and Fitness.

Start Date: Sep 83		Est Comp Date: Jan 85
Principal Investigator(s) Jeannette E. South-Paul, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Family Practice		Associate Investigators:
Key Words: Exercise, Pregnancy, Fitness		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To determine whether pregnancy causes a decrease in physical fitness as measured by maximum oxygen consumption between the second and third trimesters; and 2) to assess whether the maintenance of a regular exercise program during the second half of pregnancy will affect fitness and the outcome of the pregnancy.

Technical Approach: Graded exercise tests performed two times at 20 and 30 weeks gestation on both an exercise and a control group. Supervised exercise in PT Dept for exercise group from 20 weeks gestation on.

Subjects enrolled to date: 20

Progress: Eight controls and 12 exercise patients have been enrolled in the program and all but three have completed it. Hope to complete program by 1 Jan 85 due to difficulty in obtaining support personnel in PT Dept. Will evaluate data at that time. Preliminary evaluation done on 8 Jun 84 and presented at University of North Carolina were favorable with respect to effects of exercise during pregnancy.

"Evaluation of Exercise and Fitness in Pregnancy" presented at Department Family Medicine Annual Faculty Development Fellowship Symposium, University of North Carolina, Chapel Hill, NC, Jun 1984.

Detail Summary Sheet

Date: 2 Oct 84		Prot No.: 78-38		Status: Ongoing	
Title: Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings. Part I. Human Immunologic Reactivity to Fire Ant Antigens. BB IND 1452					
Start Date:			Est Comp Date:		
Principal Investigator(s) Chester T. Stafford, M.D., COL, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Immunology Clinical Investigation			Associate Investigators: Robert B. Rhoades, M.D., Medical College of Georgia Charles J. Hannan, Jr, PhD, CPT, MSC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Mar 83 Review Results Continue	

Study Objective: 1) To compare the skin test reactivity of fire ant venom and its components with whole body extracts (WBE) of fire ants in patients allergic to stings of the imported fire ant. 2) To compare skin test reactivity with in vitro immunologic studies (RAST and Histamine release). 3) To determine the pretreatment immunologic status of fire ant sensitive patients prior to their participation in studies comparing the relative efficacy of immunotherapy with fire ant venom (Part III protocol) versus whole body extracts (Part II protocol) versus placebo; pending DA approval. Part IV on separate summary sheet.

Technical Approach: The following imported fire ant (S. invicta) antigens have been prepared:

- 1) 96-1 ml vials of freeze-dried whole venom (1:1000 w/v after reconstitution).
- 2) 146-1 ml vials of freeze-dried front end (FE) body segment extract (1:10 w/v after reconstitution).
- 3) 145-1 ml vials of freeze-dried anterior end (AE) body segment extract (1:10 w/v after reconstitution).

Progress: No skin testing nor any other human clinical studies have yet been performed pending approval from the Food and Drug Administration, in accordance with letter dated December 20, 1983.

Detail Summary Sheet

Date: 12 Jul 84		Prot No.: 78-38		Status: Completed	
Title: Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings. Part IV - <u>In Vitro</u> Testing of Allergenic Substances. BB IND 1452.					
Start Date: Aug 79			Est Comp Date: Dec 83		
Principal Investigator(s) Chester T. Stafford, M.D., COL, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Immunology, Clinical Investigation			Associate Investigators: Charles J. Hannan, Jr, PhD, CPT, MSC Robert B. Rhoades, M.D., Medical College of Georgia		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: Parts I, II and III of this protocol will be conducted under regulations for an Investigational New Drug (IND) and; therefore, production lots of allergens produced at DDEAMC must be subjected to a series of specific evaluations. Tests to be performed include evaluation of: 1) potency, 2) general safety, 3) sterility, and 4) purity as specified in Title 21, Code of Federal Regulations.

Progress: All lots of product have now been prepared and tests, as specified in the original protocol and modified in subsequent reports, have all been completed in most lots. All tests have been completed in the remaining eleven lots and our intention is to proceed with the clinical trials using only those lots until the remaining RAST results are obtained. In last year's annual report we stated that because no hyaluronidase activity was found in lots tested at that time, that we would omit further testing for that enzyme. The reason for lack of hyaluronidase activity is still unclear, although it was repeated by another laboratory which also found no activity. We chose to measure another enzyme, N-acetyl-beta-glucosaminidase (NAG), in lieu of the hyaluronidase.

Our last annual report included results of the phospholipase A assay for potency and water content measurement for purity in all the abdominal end (AE) and front end (FE) lots. The two aqueous phase venom (AQV) lots produced since then also passed the purity test (no measurable residual moisture) and had phospholipase A activities of 800 nq/ml (AQV 7-19-83) and 500 ng/ml (AQV 8-9-83).

General safety standards were met by all lots of products. No guinea pigs or mice dies or lost weight during the testing period.

Sterility standards were met by all lots. Although some lots required retesting, the contamination was always attributable to procedural error in the sterility assay.

The investigators plan to proceed with clinical testing.

Detail Summary Sheet

Date: 10 Oct 84		Prot No.: 81-44		Status: Completed	
Title: Cardiac Rhythm Disturbances Associated With First Dose Exposure to Doxorubicin.					
Start Date: Oct 81			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators: Charles Longer, M.D., MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Nov 83 Review Results Continue	

Study Objective: To determine whether persons treated with Doxorubicin (Adriamycin) experience cardiac arrhythmias in the 24 hours after initial exposure.

Technical Approach: Holter monitoring performed 24 hours prior and post patient's first exposure to adriamycin.

Subjects enrolled to date: 25

Subjects enrolled for reporting period: None

Progress: No further patients will be entered on this study at DD Eisenhower Army Medical Center. This study is being completed by Dr. Friess at Brooke Army Medical Center, Ft Sam Houston, TX.

Detail Summary Sheet

Date: 4 Jun 84 Prot No.: 82-50 Status: Terminated
 Title: Primary Renal Hematuria: A Prospective Evaluation.

Start Date: Oct 82		Est Comp Date:
Principal Investigator(s) James A. Hasbargen, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Nephrology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Nov 83 Review Results Terminate

Study Objective: To determine the etiology and significance of hematuria, microscopic and macroscopic, as well as prognosis in patients who have neither personal or family history of renal disease, nor evidence of systemic disease or extrarenal causes of hematuria.

Technical Approach: Patients studied will be over 18 years of age and will have had either gross or microscopic hematuria (the latter defined as greater than ten red blood cells per high-powered microscopic field), intermittently or continuously for at least a three-month period. This will not include urinary tract hemorrhage, i.e., urinary hematocrit of greater than 3% or clot formation. Historical, physical exam and laboratory criteria must be met prior to the patient's entry into the study, and both the patient and the attending physician must be willing to subject the patient to a comprehensive evaluation in accordance with the protocol to include renal arteriography and renal biopsy if indicated.

Progress: Five patients enrolled, with studies completed. No untoward effects or complications.

Detail Summary Sheet

Date: 4 Jun 84 Prot No.: 82-51 Status: Terminated
 Title: IgA Nephropathy: A Prospective Evaluation.

Start Date: Oct 82		Est Comp Date:
Principal Investigator(s) James A. Hasbargen, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Nephrology Pathology		Associate Investigators: Mark Anderson, D.O., MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Nov 83 Review Results Terminate

Study Objective: To determine pathologic and clinical-pathologic criteria for the diagnosis of IgA nephropathy, the prognosis of patients with such a diagnosis and their suitability for continued military service, the extent of evaluation and degree of followup required for such patients, and the sensitivity and specificity of various noninvasive diagnostic techniques which potentially could obviate the necessity for renal biopsy.

Technical Approach: Patients studied will be over 18 years of age and will have a renal biopsy proven diagnosis of IgA nephropathy. It is realized that such a diagnosis may be made on the basis of the immunofluorescence finding of glomerular IgA deposition, and that there might be differences of opinion between various pathologists concerning diagnostic criteria for this disease entity. Attending physician and the patient must be willing to submit to a comprehensive evaluation to include long-term followup and possibly repeat renal biopsy in accordance with the protocol. Historical, physical exam and laboratory criteria must be met prior to the patient's entry into the study.

Progress: Four patients enrolled, no untoward effects or complications.

Detail Summary Sheet

Date: 8 Oct 84 Prot No.: 83-6 Status: Terminated
 Title: Treatment of Advanced Testicular Cancer With VP-16 213.

Start Date: Nov 82		Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Nov 83 Review Results Terminate

Study Objective: 1) To evaluate response rate and survival of patients with advanced, nonseminomatous germ cell neoplasms treated with combination chemotherapy with VP-16 213, vincristine, cyclophosphamide, actinomycin-D, vinblastine, bleomycin and cis-platinum. 2) To determine the toxicity of combination chemotherapy in the following areas: hematologic, gastrointestinal, pulmonary, renal, auditory, dermatologic and neurologic. 3) To develop a psycho-social profile of patients with testicular cancer prior to, during and following treatment in order to derive a more effective overall patient care plan.

Technical Approach: All patients are to be clinically staged according to staging system (Appendix A of protocol). All patients entered on this study will undergo psycho-social evaluation by written testing and by personal interview prior to initiation of each cycle of therapy and after completion of 4 cycles of therapy or at the time of discontinuation of therapy. In addition, those patients who achieve a complete remission will be re-evaluated at 6 months and at one year.

Progress: Three patients entered into study through FY 83. Terminated at WRAMC.

Detail Summary Sheet

Date: 27 Sep 84		Prot No.: 83-11		Status: Completed	
Title: Cross Reactivity of Fall Weed Pollens as Determined by RAST Inhibition Techniques.					
Start Date: Feb 83			Est Comp Date:		
Principal Investigator(s) Chester T. Stafford, M.D., COL, MC Larry Smith, M.D.			Facility: DDEAMC		
Dept/Svc: Medicine/Allergy			Associate Investigators: Charles J. Hannan, Jr, PhD, CPT, MS		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: (1) To determine if there is cross reactivity of several fall weed pollens with ragweed pollen. (2) To eliminate costly antigens used for both testing and treating with immunotherapy if significant cross reactivity is proven. (3) To propose that immunotherapy with the most positively reacting antigen will provide a rise in more clinically relevant blocking IgG antibody.

Technical Approach: High titered ragweed IgE serum will be obtained from multiple donors and pooled together after sensitivity has been shown by positive skin test reactions and/or by RAST titers. This pooled serum will then be used in a RAST inhibition test against other fall weed pollens.

Number of subjects enrolled to date: 7

Progress: Antigenic relationships of six common weed pollens (marsh elder, cocklebur, pigweed, lamb's quarters, sheep sorrel, and plantain) to ragweed were determined by using an enzyme modification of the radioallergosorbent test (RAST) inhibition procedure of Gleich, et al. Phadezym immunoassay kits were used incorporating anti-IgE conjugated to beta-galactosidase in place of standard RAST and I¹²⁵ antihuman IgE. Specimens were run in duplicate. Percent inhibition of ragweed binding was calculated and results were plotted against the concentration of the test antigen.

Ragweed and marsh elder were found to be antigenically related having similar slopes of inhibition. Higher concentrations of marsh elder were required to produce 50% inhibition. None of the other pollens produced slopes that demonstrated significant inhibition of ragweed. These findings were not unexpected as ragweed and marsh elder are both Compositae of the ragweed tribe, Ambrosieae. The other weeds studied are not as closely related as phylogenetically.

These findings suggest that there is no significant cross reactivity of most weeds with ragweed except for marsh elder. Skin testing with ragweed alone is

83-11 Continued

not adequate and immunotherapy with only ragweed will probably not be sufficient to produce a significant rise in clinically relevant blocking IgG antibody to other weed pollens.

Presented: 40th Annual Meeting, American Academy of Allergy and Immunology, Chicaco, IL, Mar 1984.

Smith L, Stafford CT, Wray BB Tillirson M, Doran D: Cross-reactivity of weed pollens with ragweed by phadezym RAST inhibition (Abstract). J Allergy Clin Immunol Jan 1984; 73(1).

The manuscript is now being completed and will soon be submitted for publication.

Detail Summary Sheet

Date: 2 Oct 84 Prot No.: 83-12 Status: Terminate
 Title: Role of Calcium Channel Blockers in Reversible Obstructive Airway Disease.

Start Date: Feb 83		Est Comp Date:
Principal Investigator(s) Chester T. Stafford, M.D., COL, MC Larry Smith, M.D. Kenneth D. Weeks, M.D., LTC, MC		Facility: DDEAMC
Dept/Svc: Medicine Allergy Clinic, Pulmonary Lab		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: (1) To determine if calcium channel blockers have any measureable effects on airway resistance. (2) To determine if patients suffering from both myocardial diseases and Reversible Obstructive Airway Disease (ROAD) will have improvement in symptoms of ROAD when treated with calcium channel blockers.

Technical Approach: Pre and post calcium channel blocker treatment pulmonary function tests will be obtained. This will be done in the Pulmonary Function Lab after the patients have been sent to the Allergy Clinic from Cardiology. No blood will be obtained and no other laboratory procedures will be performed. All patients will be over 21 years old and have a cardiac disease which requires a calcium channel blocking agent. Some will also have a diagnosis of ROAD.

Number of subjects enrolled to date: 1
 Number of subjects enrolled for reporting period: none.

Progress: All investigators have left the service, terminate study.

Detail Summary Sheet

Date: 4 Jun 84		Prot No.: 83-14		Status: Terminated	
Title: Urinary Tract Disease in Patients With Hematuria on Chronic Anti-coagulation, A Prospective Analysis.					
Start Date: Feb 83			Est Comp Date:		
Principal Investigator(s)			Facility:		
James J. Baunchalk, M.D., CPT, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Nephrology					
Key Words:					
Accumulative MEDCASE		Est Accumulative		Periodic Apr 84	
Cost:		OMA Cost:		Review Results Terminate	
Study Objective: To determine the incidences of significant renal disease in patients who have hematuria while on chronic anticoagulation.					

Technical Approach: Patients will be selected from the anticoagulated population at DDEAMC and be followed weekly with PT's and U/A's.

Progress: None. Unable to find new PI to take over this study; therefore, it is terminated.

Detail Summary Sheet

Date: 28 Sep 84 Prot No.: 83-22 Status: Ongoing
 Title: Use of Isotretinoin in Prevention of Basal Cell Carcinoma.

Start Date:	Est Comp Date:
Principal Investigator(s) Marshall A. Guill, M.D., LTC, MC	Facility: DDEAMC
Dept/Svc: Medicine/Dermatology	Associate Investigators: James K. Aton, Jr., M.D., COL, MC John R. Cook, M.D., LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To evaluate the effectiveness of low dosage levels of isotretinoin in reducing the incidence of basal cell carcinomas in a high risk population. To examine possible side effects associated with long term administration of low doses of isotretinoin.

Technical Approach: Patients with two or more basal cells in the past three years are eligible for inclusion in the study. After a thorough physical exam, participants are randomized to either the treatment group or the placebo group. The medication is provided by the National Cancer Institute and is double-blinded. We hope to enroll about 150 patients over the first 18 months of the study. Participants take the medication for 36 months, continuing to be followed for the following 24 months for a total of 60 months in the study. Funding in the amount of \$40,000 was provided through an interagency agreement between DDEAMC and the National Cancer Institute. At the present time, we have utilized less than \$1,000. Funds expended have been for one TDY trip to meet with other investigators in Bethesda and for a camera for use in the study. The majority of the monies were to be used for the salary of a study coordinator. The position of the study coordinator has remained unfilled. Civilian Personnel has been attempting to fill the position for almost 12 months. Most of the remaining monies will have to be returned to the NCI at the end of the current fiscal year.

Because we have not been able to hire a study coordinator, we have enrolled no patients. We have collected a list of candidates to be screened but time constraints, and clinical commitments have not permitted us to actually begin the study.

Progress: During the past year, we met with other study coordinators in conference at the National Institute of Health in Bethesda, MD. We began collecting a list of possible candidates to be screened for participation in the study. A job description for the study coordinator was drafted and submitted to Civilian Personnel so that the position would be filled as expeditiously as possible. Furniture for the office of the study coordinator was ordered. A telephone line was placed in the office of the coordinator.

83-22 Continued

The problems dealing with the Civilian Personnel Office in trying to hire a study coordinator have been most frustrating. I am frankly surprised that the NCI has not replaced us with another institution. I would recommend that command interest be directed in ways to alleviate red tape and expedite hiring processes in cases where grants are concerned and time is of the essence. There seems to be a lack of appreciation on the part of the Civilian Personnel Office of the problems of clinical investigation and the need to pursue studies in a timely and scheduled manner.

The committee should be reluctant to approve studies of this nature in the future if necessary personnel cannot be hired expeditiously. It puts the institution in an embarrassing position and reflects poorly on our abilities when we enter into a collaborative study and then fail to follow through in a timely manner.

Detail Summary Sheet

Date: 26 Jun 84 Prot No.: 83-25 Status: Terminated
 Title: Nitroglycerin in the Treatment of Pain Caused by Ureteral Calculi.

Start Date: Jul 83	Est Comp Date:
Principal Investigator(s) CPT Mark Kozakowski, D.O., CPT, MC Gary Wikert, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine/Nephrology, Urology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Mar 84 Review Results Terminate

Study Objective: To determine the efficacy of nitroglycerin (NTG) in the relief of pain secondary to the passage of ureteral calculi. Additionally, to assess the ability of NTG to facilitate passage of ureteral calculi.

Technical Approach: Administer placebo and NTG to patients with ureteral colic in a randomized, double blind crossover study. Assess pain relief on a 1 - 10 scale and note time of passage of stone.

Progress: Four patients enrolled through FY 83; no enrollments in FY 84. Terminate.

Detail Summary Sheet

Date: 21 Aug 84		Prot No.: 83-35		Status: Terminate	
Title: Esophageal Reflux in Patients with Mixed Connective Tissue Disease (MCTD).					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Robert H. Peters, MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Gastroenterology					
Key Words:					
Accumulative MEDCASE		Est Accumulative		Periodic Jul 84	
Cost:		OMA Cost:		Review Results Continue	
Study Objective: To quantitate reflux in patients with MCTD.					

Technical Approach: Esophageal motility and 24* pH monitoring at reflux.

Progress: Clinical responsibility and ongoing research for another protocol has necessitated not continuing with this study. Terminate.

Detail Summary Sheet

Date: 7 Jul 84 Prot No.: 84-2 Status: Transfer
 Title: Chronic Respiratory Acidosis and Bone Disease.

Start Date: Nov 83	Est Comp Date: Jun 87
Principal Investigator(s) William E. Duncan, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine/Endocrinology	Associate Investigators: Robert B. Chadband, M.D., MAJ, MC William Johnson, M.D., LTC, MC Robert Ranlett, M.D., MAJ, MC Robert E. Morrison, M.D., COL, MC Robert Weinstein, M.D.
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: To study the extent of bone disease, if any, and the parameters of calcium homeostasis of patients with chronic respiratory acidosis.

Technical Approach: Parameters of calcium metabolism and bone densitometry are to be determined in nonacidotic and acidotic patients with COPD.

Progress: Approximately 3,000 pulmonary function tests were reviewed to identify potential study subjects. However, because of the impending transfer of the principal investigator, this study was suspended. This study will be submitted to the Institutional Review Committee at Walter Reed Army Medical Center if associate investigators can be found to participate in this study.

Detail Summary Sheet

Date: 7 Jul 84	Prot No.: 84-26	Status: Transfer
Title: Vitamin D Substrate Availability in Primary Hyperparathyroidism.		
Start Date: Apr 84	Est Comp Date: Jun 87	
Principal Investigator(s) William E. Duncan, MD, MAJ, MC	Facility: DDEAMC	
Dept/Svc: Medicine/Endocrinology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective: To study the 25-hydroxyvitamin E metabolism in patients with primary hyperparathyroidism.		

Technical Approach: To measure vitamin D metabolites before and after receiving oral 25-hydroxyvitamin D.

Progress: To date, one patient has completed this study without adverse reactions. Two other patients with primary hyperparathyroidism are scheduled to start this protocol. Because of the transfer of the principal investigator, it is necessary to transfer this project to Walter Reed Army Medical Center to complete this project.

Detail Summary Sheet

Date: 7 Jul 84		Prot No.: 84-27		Status: Transfer	
Title: A Glucose-Clamped Tolbutamide Test for Insulin-Secreting Islet Cell Tumors.					
Start Date: Mar 84			Est Comp Date: Jun 87		
Principal Investigator(s) William E. Duncan, MD, MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Endocrinology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To compare the glucos-clamped tolbutamide test to the three day fast to diagnose insulin-secreting neoplasms.

Technical Approach: After a pateint has been diagnosed as having an insulin-secreting neoplasm by conventional means (three day fast), patient is asked to undergo a glucose-clamped tolbutamide test.

Progress: One patient has been studied since the starting date of this protocol. There have been no adverse reactions. These test results have been included with those from six other patients with islet cell tumors and a manuscript has been prepared and submitted for publication. Because of the transfer of the principal investigator, this protocol will be transferred to Walter Reed Army Medical Center.

Detail Summary Sheet

Date: 1 Oct 84 Prot No.: 84-51 Status: Ongoing
 Title: DIPLOS-04 Pacemaker Investigation

Start Date: Oct 83		Est Comp Date:
Principal Investigator(s) John D. Rathbun, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Cardiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: The DIPLOS-04 protocol is a clinical validation study utilizing the BIOTRONIK DIPLOS 04 Dual Chamber Pulse Generator. This study is being conducted under an investigational device exemption and consists of 20 centers and 20 investigators.

Technical Approach: This study is designed using patients who will require use of dual chamber DDD pacing. The pacemakers are inserted for the Cardiology Service utilizing the Cardiac Catheterization Laboratory, Cardiac Catheterization Laboratory Technologists and the Cardiology Service. Funding is provided from the usual sources for the implantation of pacemakers. Three subjects have been enrolled to date and this is the total enrolled for the reporting period since the initiation of this study. As of this date, there has been no significant adverse reaction, although one patient died three days after the implantation of the permanent pacemaker secondary to non-pacemaker related causes (patient with cardiomyopathy and cardiac sudden death secondary to ventricular tachyarrhythmias).

Progress: This study is presently ongoing until approximately 100 DIPLOS-04 generators are implanted nationwide. At the present time, there have been approximately 70-80 generators implanted. The results of the DIPLOS-04 dual chamber pacemaker implantations have been very satisfying to date, and demonstrated a sturdy pacemaker with no basic dangers or nuisance flaws. As for pacemaker-mediated tachycardia, this has not been observed as a complication secondary to the program ability of atrial refractory up to 500 milliseconds. In addition, the AV delay fallback mechanism allows increased sinus node activity and fast atrial rates with flexibility in the program ability of the AV delay.

Detail Summary Sheet

Date: 1 Oct 84 Prot No.: 82-3 Status: Ongoing
 Title: SWOG 7823/24/25/26 ROAP-AdOAP in Acute Leukemia, Phase III.

Start Date:	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Nov 83 Review Results Continue
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Study Objective: 1) To compare the efficacy of the 4-drug combination chemotherapy regimen, ROAP (Rubidazone, vincristine, arabinosyl cytosine, and prednisone) to AdOAP (the same combination using Adriamycin in place of Rubidazone) in adult acute leukemia, as determined by remission rate, remission duration and survival. 2) To determine the comparative toxicity of these regimens. 3) To determine whether late intensification therapy at nine months after complete remission will improve long-term, disease-free survival. 4) To determine whether immunotherapy using levamisole for six months after 12 months of complete remission on chemotherapy improves disease-free survival. 5) To determine the effects of intrathecal Ara-C on the incidence of CNS leukemia. 6) To determine reproducibility of the FAB/histologic classification and correlation to response to therapy in 200 consecutive cases of acute leukemia. 7) To study the effects of intensive supportive care in the management of acute leukemia.

Technical Approach: All patients over 15 with a diagnosis of acute leukemia who have not received extensive therapy (defined as more than one course of any other chemotherapeutic agent or combination of agents) will be eligible for this study. The diagnosis of acute leukemia will be made on bone marrow smear, clot section and/or biopsy. An absolute infiltrate of 50% leukemic cells or greater is required.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84 Prot No.: 82-4 Status: Ongoing
 Title: SWOG 8001, Evaluation of Two Maintenance Regimens in the Treatment of Acute Lymphoblastic Leukemia in Adults, Phase III.

Start Date:	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D.; MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Nov 83 Review Results Continue

Study Objective: 1) To evaluate the effectiveness as determined by the complete remission rate of the L10 protocol using Vincristine, Prednisone and Adriamycin for induction, followed by intensive consolidation in the treatment of acute ALL. 2) To compare the effect on remission duration and survival of two maintenance regimens: the L10 "eradication" regimen vs cyclic therapy with POMP-COAP-OPAL. 3) To determine the reproducibility of the FAB histologic classification and correlation to response to therapy of ALL in adults.

Technical Approach: Patients are eligible with the diagnosis of acute lymphoblastic leukemia who satisfy the following criteria: A) Absolute infiltration of the marrow with >50% blasts; absolute infiltration is defined as the total blast cell percentage (%) multiplied by the bone marrow cellularity percentage divided by 100. B) If the absolute infiltrate is 30-49%, evidence of progressive disease prior to entering the study will be required. Therapy will follow the schema outlined in the protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84 Prot No.: 82-5 Status: Ongoing
 Title: SWOG 7827, Combined Modality Therapy for Breast Cancer, Phase III.

Start Date:		Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Nov 83 Review Results Continue

Study Objective: 1) To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus chemotherapy and oophorectomy. 2) To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, using one versus two years of combination chemotherapy alone. 3) To compare the disease-free interval and recurrence rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy. 4) To compare the effects of these various adjunctive therapy programs upon the survival patterns of such patients. 5) To correlate the ER status with disease-free interval and survival.

Technical Approach: All patients must have had a radical of modified radical mastectomy with histologically proven breast cancer and with one or more pathologically proven axillary nodes. Primary neoplasm and clinically apparent axillary disease must be completely removed. Pretherapy studies must reveal no evidence of metastatic disease or involvement of the other breast. Patients with postoperative radiation therapy are eligible but will be randomized and evaluated separately. Therapy will follow the schema outlined in the protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84 Prot No.: 82-7 Status: Ongoing
 Title: SWOG 7808, Combined Modality Treatment for Stage III and IV Hodgkin's Disease MOPP #6, Phase III.

Start Date:		Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Nov 83 Review Results Continue

Study Objective: To attempt to increase the complete remission rate induced with MOB-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a partial response at the end of six cycles of MPO-BAP. 2) To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission durations over a no further treatment group when complete response has been induced with six cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

Technical Approach: Eligible patients must have a histological diagnosis of Hodgkin's which must be classified by the Lukes and Butler system. Therapy will follow the schema outlined in the protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84 Prot No.: 82-8 Status: Closed
 Title: SWOG 8027, The Natural History of Pathological Stage T₁₋₂N₀M₀ER+ Breast Cancer, Phase III.

Start Date: Jan 82		Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Nov 83 Review Results Terminate

Study Objective: To document recurrence-rates, patterns of recurrence, and survival among patients with Stage I or Stage II node negative (T₁₋₂N₀M₀) breast cancer whose tumors are determined to be estrogen receptor positive at the time of surgery.

Technical Approach: All female patients having had a radical, modified radical, or adequate local excision, with axillary node dissection for histologically proven breast carcinoma, whose axillary nodes are negative for tumor, and whose estrogen receptor assay on the primary tumor is positive are eligible for this study.

Progress: One patient was entered for natural history follow-up and still remains on study. Study closed to further patient registration.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 82-9		Status: Ongoing	
Title: SWOG 7804, Adjuvant Chemotherapy With 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs Surgery Alone for Patients With Locally Advanced Gastric Adenocarcinoma, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Nov 83	
				Review Results Continue	

Study Objective: To determine the efficacy of adjuvant chemotherapy with 5-FU, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TNM stage-groups IB, IC and III gastric adenocarcinoma compared to potentially curative surgery alone.

Technical Approach: Eligible patients must have localized lesions at least extending into the submucosa and involving any of the deeper layers with the maximum allowable penetration into but not through the serosa; localized lesions extending through serosa, with or without direct extension to contiguous structures; a lesion diffusely involving the wall of the stomach with or without metastases to immediately adjacent perigastric nodes or a localized lesion of any depth with metastases to perigastric nodes in the immediate vicinity; a localized or diffuse lesion with metastases to perigastric nodes distant from primary, e.g., greater curvature lesion with metastases to superior gastric nodes (Group II) on lesser curvature.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84	Prot No.: 82-10	Status: Ongoing
Title: SWOG 8006, Preoperative Reductive Chemotherapy for Stage III or IV Operable Epidermoid Carcinoma of the Oral Cavity, Oropharynx, Hypopharynx or Larynx, Phase III.		
Start Date: Jan 82	Est Comp Date:	
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC	
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Nov 83 Review Results Continue

Study Objective: To determine the length of remission, recurrence-rates, survival-rates, and pattern of recurrence for patients receiving therapy utilizing surgery and postoperative radiation vs combined therapy utilizing preoperative chemotherapy, surgery and postoperative radiation therapy in operable Stage III or IV epidermoid carcinoma of the head and neck.

Technical Approach: Patients with operable lesions will be randomized between two therapeutic programs: Arm I - combined therapy including surgery and postoperative radiation therapy; or Arm 2 - combination chemotherapy followed by surgery and radiation therapy. Patients randomized to the chemotherapy limb will receive three courses of chemotherapy consisting of cis-platinum, methotrexate, vincristine and bleomycin.

Progress: One patient enrolled. No reportable data.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-10		Status: Ongoing	
Title: SWOG 7984, Treatment of Chronic Stage CML With Pulse, Intermittent Busulfan Therapy With or Without Oral Vitamin-A, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the efficacy of standard pulse, intermittent busulfan therapy plus oral vitamin A in prolonging the chronic phase of CML, and hence in prolonging survival.

Technical Approach: All patients with newly diagnosed chronic stage CML will be eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-11		Status: Ongoing	
Title: SWOG 7990, Intergroup Testicular Study (A cooperative study of Stage I and II testicular cancer of germ cell origin using Bleomycin, Vinblastine, Cis-Platinum).					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To compare the disease-free survival and overall survival for surgery alone (with chemotherapy for relapsers) versus surgery plus early adjuvant chemotherapy in patients with resectable Stage II testicular cancer. 2) To register and follow patients with non-seminoma, non-choriocarcinoma Stage I testicular cancer, to define prognostic variables which may predict recurrence in this stage group. 3) To define the difference in disease-free rates and patterns of recurrence, based upon histologic subtypes and extent of disease on initial presentation. 4) To evaluate the role of marker substances such as: human chorionic gonadotrophin (BHCG), alpha-fetoprotein (AFP) and lactic dehydrogenase (LDH) in the early detection and management of recurrence in patients with Stage I and Stage II testicular carcinoma. 5) To evaluate the accuracy of lymphangiograms, CAT scans, and ultrasound studies for staging of retroperitoneal nodal involvement.

Technical Approach: Patients with histologically confirmed carcinoma of the testis, stage I or stage II, are eligible. Patients should enter the study between two and four weeks after lymphadenectomy. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-12		Status: Closed	
Title: SWOG 8025, Combination Chemotherapy for Chronic Lymphocytic Leukemia, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To determine the response-rate and duration of remission in patients with CLL treated with combination chemotherapy consisting of Prednisone, Vincristine, Cytosine Arabinoside, Cytosan, and Adriamycin. To be eligible for treatment, patients must have evidence of marrow failure (Rai Stage 3 or 4) or rapidly progressive disease. 2) To correlate parameters obtained in the clinical, pathological, and immunological staging with response to treatment. 3) To determine the effect of stopping chemotherapy after patients have achieved a complete remission plus 2 consolidation courses, in order to define a cured or stabilized fraction of patients.

Technical Approach: All patients who fulfill the criteria for diagnosis of chronic lymphocytic leukemia according to the Rai Classification will be eligible for registration. Therapy will follow the schema outlined in the study protocol.

Progress: One patient was entered, then taken off on 7 Dec 83. Patient expired on 31 Dec 83. Study closed to further patient registration.

Detail Summary Sheet

Date: 1 Oct 84 Prot No.: 84-13 Status: Closed
 Title: SWOG 8038, Vinblastine in Advanced Ovarian Cancer, Phase II.

Start Date:		Est Comp Date:
Principal Investigator(s) Medicine/Hematology-Oncology		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To determine the response-rate and remission duration with intravenous therapy using Velban as a continuous infusion in patients with advanced ovarian cancer. 2) To define further the qualitative and quantitative toxicity of the continuous infusion of Velban.

Technical Approach: To be eligible, patients must have histologically confirmed, advanced, incurable ovarian cancer who are refractory to or ineligible for treatment on Southwest Oncology Group protocols of higher priority. Patients must have measurable disease and life expectancy of six weeks or more. Therapy will follow the schema outlined in the study protocol.

Progress: No patients enrolled at DDEAMC. Study closed to further patient registration.

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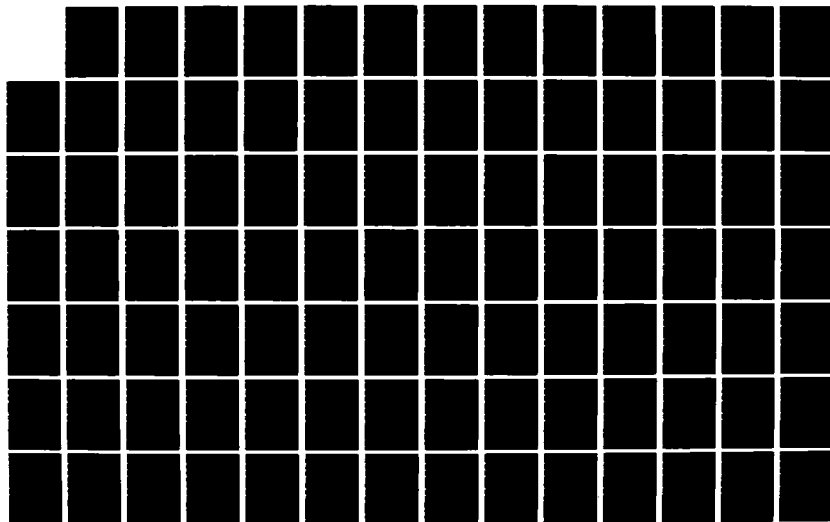
CLINICAL INVESTIGATION PROGRAM RCS MED-300 (RI)(U)
DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER FORT GORDON
GA DEPT OF CLINICAL INVESTIGATION K M PLOWMAN OCT 84

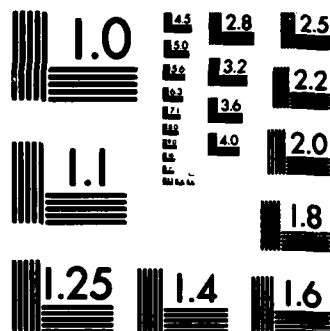
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Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-14		Status: Ongoing	
Title: SWOG 8102, Whole Brain Irradiation and Intrathecal Methotrexate in the Treatment of Solid Tumor Leptomeningeal Metastases, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the response-rate (CR + PR) of intrathecal methotrexate and whole brain irradiation in the control of solid tumor leptomeningeal metastases.

Technical Approach: All patients must have cerebrospinal fluid which is cytologically positive for malignant cells. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84	Prot No.: 84-15	Status: Ongoing
Title: SWOG 8110, Treatment of Advanced Germ Cell Neoplasms of the Testis: A Comparison of Remission Induction With Vinblastine, Bleomycin and Cis-Platinum vs Vinblastine, Cis-Platinum and VP-16-213; Surgical Removal of All Residual Tumor Following Remission Induction; Comparison of Maintenance Therapy With Cyclophosphamide, Actinomycin-D, Adriamycin and Vinblastine vs Observation, Phase III.		
Start Date:	Est Comp Date:	
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC	
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To compare in a randomized fashion the effectiveness of the drug combination Vinblastine, Cis-diamminedichloroplatinum (Cis-platinum) and VP-16-213 versus Vinblastine, Bleomycin and Cis-Platinum in the remission induction of patients with disseminated germ cell neoplasms of testicular origin. 2) To determine the role of six months of maintenance chemotherapy versus observation for those patients who achieve a complete response during induction, or have a totally resected mature teratoma, in terms of relapse-free survival and overall survival. 3) To determine the role of six months of maintenance chemotherapy versus observation for those patients with residual carcinoma having no evidence of disease following surgery, in terms of relapse-free survival and overall survival. 4) To document the nature and extent of the hematologic and non-hematologic side effects of the treatment modalities.

Technical Approach: Patients should have a histologically confirmed diagnosis of disseminated germ cell neoplasms of testicular origin. All patients with bulky abdominal disease (Stage cII (N₄) or Stage cIII) will be eligible for the study. Patients should have an expected survival of at least eight weeks. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-16		Status: Ongoing	
Title: SWOG 8211, Evaluation of Cis-Diamminedichloroplatinum in Disseminated Gastric Adenocarcinoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To test the response-rate of cis-diamminedichloroplatinum (DDP) in patients with disseminated and measureable adenocarcinoma of the stomach who are previously untreated. 2) To test the response-rate of cis-diamminedichloroplatinum in patients with disseminated adenocarcinoma of the stomach who are previously treated with 5-fluorouracil, Adriamycin and Mitomycin-C (5-FAM) chemotherapy.

Technical Approach: Eligible patients must have a histologically proven gastric adenocarcinoma and be considered inoperable for cure at the time of entry on the study. Patients must have a life expectancy of six weeks or longer. Therapy will follow the schema outlined in the study protocol.

Progress: One patient was entered on study, then taken off.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-17		Status: Ongoing	
Title: SWOG 8232, Treatment of Limited Small Cell Lung Cancer With VP-16/ Cis-Platinum, Alternating with Vincristine/Adriamycin/Cyclophosphamide and Radiation Therapy Versus Concurrent VP-16/Vincristine/Adriamycin/Cyclophosphamide and Radiation Therapy, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To compare the efficacy of alternating non-cross-resistant, multidrug regimens with concurrent combination chemotherapy as remission induction in patients with limited small cell lung carcinoma. 2) To determine the toxicity of these treatment programs.

Technical Approach: All patients must have histologically proven small cell carcinoma of the lung. Prior to treatment, patients should be staged as to the extent of disease. Only patients with limited disease are eligible for this study. They must have evaluable or measurable disease. Patients having a prior surgical procedure are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-18		Status: Ongoing	
Title: SWOG 8237, Evaluation of Continuous Infusion Vinblastine Sulfate in Pancreatic Adenocarcinoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To determine the clinical response rate of a five-day continuous infusion of vinblastine sulfate in pancreatic adenocarcinoma.

Technical Approach: To be eligible, patients must have a pathologically verified diagnosis of pancreatic adenocarcinoma. They must have objectively measurable or evaluable lesion(s) excluding CNS metastases and a life expectancy of at least eight weeks. Patients must have recovered from the toxicities of previous chemotherapy and/or radiotherapy and have demonstrated progressive disease. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-19		Status: Ongoing	
Title: SWOG 8241, Treatment for Advanced Non-Small Cell Lung Cancer: PV _p Versus PV _p M Versus PVE Versus PVEMi Versus FOMi/CAP, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To directly compare the efficacy and toxicity of Cis-platinum plus VP-16 (PV_p) versus Cisplatinum plus Vinblastine (PVE) in patients with advanced (TNM Stage III M1) non-small cell lung cancer (NSCLC). 2) To compare the response rate, response duration, survival and toxicity of Cis-platinum plus VP-16 (PV_p) to Cis-platinum plus VP-16 plus MGBG (PV_pM). 3) To compare the response rate, response duration, survival and toxicity of Cis-platinum plus Vinblastine (PVE) to Cis-platinum plus Vinblastine plus Mitomycin-C (PVEMi). 4) To re-evaluate and compare the activity of FOMi/CAP to PV_p, PV_pM, PVE and PVEMi using a five-arm, randomized study design. 5) To evaluate differences in response rates among patients with squamous cell carcinoma, adenocarcinoma or large cell undifferentiated carcinoma of the lung.

Technical Approach: All patients with a histologically or cytologically confirmed diagnosis of squamous cell carcinoma, adenocarcinoma or large cell carcinoma of the lung are eligible for this study. The patient's clinical presentation should be compatible with a neoplasm of bronchogenic origin. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-20		Status: Ongoing	
Title: SWOG 8294, Evaluation of Adjuvant Therapy and Biological Parameters in Node Negative Operable Female Breast Cancer, Intergroup Study.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) Assess the impact of short-term intensive chemotherapy with CMFP to prevent disease recurrence and prolong survival in N- patients with any size ER- tumors and N- patients with ER+ tumors whose pathological size is greater than or equal to 3 cm. 2) Assess the impact of surgical procedures, ER status, menopausal status and tumor size. 3) Develop guidelines referable to histopathological features of N- tumors which are reproducible and assess their prognostic impact for disease-free survival and survival. 4) Assess the value of CEA in predicting recurrence and survival rates. 5) Assess the natural history of a subgroup with N-, ER+ small tumors (<3 cm).

Technical Approach: All female patients having had at least a total mastectomy with an axillary dissection or total mastectomy with low axillary dissection for potentially curable breast carcinoma as defined in this protocol and having no histopathological evidence of axillary node involvement will be considered for inclusion in this study. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-21		Status: Ongoing	
Title: SWOG 8302, Phase II Study of Doxorubicin, Mitomycin-C, 5-Fluorouracil in the Treatment of Metastatic Adenocarcinoma of the Prostate.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To test the effectiveness and toxicity of DMF (Doxorubicin, Mitomycin-C and 5-Fluorouracil) in the treatment of Stage D ₂ adenocarcinoma of the prostate.					

Technical Approach: Patients with histologically proven, metastatic adenocarcinoma of the prostate with measurable disease are eligible. Patients with blastic bone lesions on x-ray as a sole manifestation of metastases are not eligible. However, patients with bone metastases only who have positive bone scans will be eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-29		Status: Closed	
Title: SWOG 7925, Chemoimmunotherapy in Stages III and IV Ovarian Carcinoma: A-C + BCG, vs A-C + Cis-Platinum vs A-C + Cis-Platinum + BCG, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, MD, MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: 1) To compare the effectiveness of the Southwest Oncology Group's study, SWOG 7524 best therapy arm - A-C + BCG, vs A-C + Cis-Platinum, for remission induction and/or maintenance of disease-free status and prolongation of survival duration in patients with Stages III and IV ovarian carcinoma (measurable and non-measurable disease). 2) To compare the effectiveness of A-C + Cis-Platinum vs A-C + Cis-Platinum + BCG for remission induction and/or maintenance of disease-free status and prolongation of survival in patients with Stage III and IV ovarian carcinoma (measurable and non-measurable disease). 3) To compare the effectiveness of A-C + Cis-Platinum + BCG for remission induction and/or maintenance of disease-free status and prolongation of survival duration in patients with Stages III and IV ovarian carcinoma. 4) To compare the toxicities of the A-C + BCG, A-C + Cis-Platinum and A-C + Cis-Platinum + BCG regimens.					

Technical Approach: Only patients with epithelial type neoplasms will be eligible for this study. The patient must have histologically confirmed diagnosis of ovarian carcinoma. Therapy will follow the schema outlined in the study protocol.

Progress: No patients were enrolled, study closed to further patient registration.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-30		Status: Closed	
Title: SWOG 7956, Study of Postinfarction Nephrectomy and Medroxyprogesterone Acetate (Depo-Provera) in Metastatic Renal Cell Carcinoma.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, MD, MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To determine the response rate and survival patterns in patients with disseminated renal cell carcinoma treated with postinfarction nephrectomy. 2) To determine the response rate and survival patterns of patients with disseminated renal cell carcinoma who relapse or do not respond to postinfarction nephrectomy when treated with Depo-Provera.

Technical Approach: Patients with measurable disseminated renal cell carcinoma who have not had removal of the primary cancer and in whom the metastatic disease is not resectable at the time of nephrectomy are eligible. Patients must have an expected survival of at least 3 months. Therapy will follow the schema outlined in the study protocol.

Progress: No patients enrolled, study closed to further patient registration.

Detail Summary Sheet

Date: 1 Oct 84 Prot No.: 84-31 Status: Ongoing
 Title: SWOG 7983, Radiation Therapy in Combination with CCNU in Patients with Incompletely Resected Gliomas of the Brain, Grade I and II.

Start Date:		Est Comp Date:
Principal Investigator(s)		Facility:
Steven A. Madden, MD, MAJ, MC		DDEAMC
Dept/Svc:		Associate Investigators:
Medicine/Oncology		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To compare the survival of patients with incompletely resected Grade I and II gliomas treated with radiation alone versus radiation and CCNU. 2) To compare the effectiveness of radiation therapy versus radiation therapy plus CCNU for remission induction and duration of remission.

Technical Approach: Patient with histologically confirmed primary brain tumors of the following histologic types are eligible: Astrocytoma, Grade I and II with incomplete tumor resection. Patients who have had surgery with histologic diagnosis within the previous six weeks are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84 Prot No.: 84-32 Status: Closed
 Title: SWOG 8017, 5-FU, Adriamycin, Streptozotocin and Cyclophosphamide (FAC-S) in the Treatment of Metastatic Carcinoid Tumors, Phase II.

Start Date:	Est Comp Date:
Principal Investigator(s) Steven A. Madden, MD, MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine/Oncology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: 1) To determine whether combination chemotherapy employing 5-FU, Cyclophosphamide, Adriamycin and Streptozotocin is effective in the management of metastatic carcinoid. 2) To study the duration of survival of patients with metastatic carcinoid tumor treated with combination chemotherapy regimens. 3) To provide further information concerning the response and/or survival of patients with metastatic carcinoid originating in different sites and having different metastatic patterns.

Technical Approach: All patients must have biopsy-proven carcinoid tumor not amenable to further surgical therapy with no prior chemotherapy. A minimum life expectancy of 6 weeks and a performance status of 3 or better per Southwest Oncology Group criteria is necessary. All patients must have objectively measurable disease either as a measurable lesion or significant biochemical abnormality specific for their tumor. Therapy will follow the schema outlined in the study protocol.

Progress: No patients enrolled, study closed to further patient registration.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-33		Status: Ongoing	
Title: SWOG 8024, Combined Modality Therapy for Disseminated Soft Tissue Sarcomas, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, MD, MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To compare the effectiveness of bolus administration of Adriamycin and DTIC, to continuous infusion administration of Adriamycin and DTIC, in remission induction of patients with disseminated soft tissue sarcomas. 2) To compare the toxicities of these two drug schedules. 3) To determine the feasibility on a group-wide basis of surgical excision of accessible lesions in partially responding patients. 4) To compare the histology of the diagnostic lesion with the histology of tumor removed from the partial responder.

Technical Approach: Patients with a biopsy confirmed diagnosis of a soft tissue sarcoma with convincing clinical or biopsy-documented evidence of metastatic disease are eligible for this study. Patients must not have received any prior chemotherapy with the agents used in this study. Patients must have a life expectance of 10 weeks, and all patients must have lesion(s) which is measurable and can be followed for tumor response. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-34		Status: Ongoing	
Title: SWOG 8026, Cis-Platinum in the Treatment of Refractory Epidermoid Carcinoma of the Penis, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, MD, MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine response-rate and survival in patients with advanced epidermoid carcinoma of the penis treated with Cis-Platinum.

Technical Approach: Patients must have epidermoid carcinoma of the penis confirmed by biopsy, Stage III or IV, refractory to surgery and radiotherapy. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-35		Status: Closed	
Title: SWOG 8037, Combined Therapies for Squamous Cell Carcinoma of the Esophagus, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, MD, MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To determine the feasibility and toxicity of combined radiotherapy and chemotherapy with 5-fluorouracil and cis-platinum followed by surgery in patients with epidermoid carcinoma of the middle or distal esophagus. 2) To determine the time to local or distant progression in patients treated by these three combined modalities. 3) To determine the survival of patients treated by these three combined modalities. 4) To determine the response-rate by clinical and pathological staging at the time of surgery.

Technical Approach: Previously untreated patients with biopsy-proven squamous cell carcinoma of the middle or distal esophagus are eligible. Patients must be judged medically to be a surgical candidate for laparotomy and thoracotomy. Patients must have a life expectancy of 6 weeks or greater. Therapy will follow the schema outlined in the study protocol.

Progress: Two patients entered on study with one patient taken off study on 1 Mar 84; expired 25 May 84. One patient remaining on study. Study closed to further patient registration.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-36		Status: Ongoing	
Title: SWOG 8049, The Treatment of Resected, Poor Risk Prognosis Malignant Melanoma: Stage I: Surgical Excision vs Surgical Excision + Vitamin A, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, MD, MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To determine the efficacy of surgical excision or surgical excision plus vitamin A in preventing the recurrence of high risk, Stage I malignant melanoma by determination of remission or disease-free interval. 2) To determine the immunocompetence of patients with malignant melanoma and to determine the influence of vitamin A upon that immunocompetence.

Technical Approach: All patients with a histologically-confirmed diagnosis of high risk Stage I malignant melanoma who have not been previously treated with chemotherapy, radiation therapy, or immunotherapy are eligible. All patients must have had a wide local excision of the primary lesion. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84	Prot No.: 84-37	Status: Ongoing
Title: SWOG 8092, Use of Human Tumor Cloning System to Select Chemotherapy for patients with Ovarian Cancer Refractory to Primary Therapy, Ancillary Study.		
Start Date:	Est Comp Date:	
Principal Investigator(s) Steven A. Madden, MD, MAJ, MC	Facility: DDEAMC	
Dept/Svc: Medicine/Oncology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To utilize the human tumor cloning assay to select single agent chemotherapy for patients with epithelial-type ovarian cancer, refractory to standard therapy. 2) To determine if the human tumor cloning system can be utilized to select individual patient's therapy in a cooperative group setting.

Technical Approach: Eligible patients must have a pathological diagnosis of epithelial-type ovarian cancer in pleural or peritoneal fluid. Patients should have measurable disease and a life expectancy of at least 3 months.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-38		Status: Ongoing	
Title: SWOG 8093, Treatment of Metastatic Malignant Mesothelioma: A Comparison of Cyclophosphamide (Cytosan), DTIC and Adriamycin (CIA) vs Cyclophosphamide and Adriamycin (CA), Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, MD, MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the effect of the drug combination, Cyclophosphamide, DTIC, and Adriamycin vs Cyclophosphamide and Adriamycin (CA) on response-rate, remission duration, and survival of patients with metastatic malignant mesothelioma in a prospective, randomized Phase III clinical trial. To determine the qualitative and quantitative toxicities of these two drug combinations. To conduct an epidemiologic survey on all patients designed to identify important environmental factors which may place an individual at risk for the development of malignant mesothelioma.

Technical Approach: All patients must have histologically proven malignant mesothelioma of pleural or peritoneal origin with evidence of distant metastases or documented failure to previous radiation therapy. There must be an expected survival of at least 8 weeks. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-39		Status: Ongoing	
Title: SWOG 8094, Radiotherapy with and without Chemotherapy for Malignant Mesothelioma Localized to One Hemithorax, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, MD, MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To evaluate in a randomized prospective manner, the efficacy of Adriamycin in improving the disease-free interval in patients who will receive hemithoracic radiotherapy for Stage I pleural mesothelioma. 2) To further define prospectively the efficacy of radiotherapy to the involved hemithorax in patients with pleural mesothelioma.

Technical Approach: Eligible patients will have histologically confirmed malignant mesothelioma of the pleural cavity. Patients with measurable disease or evaluable disease as well as those in whom all gross disease has been resected will be eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-40		Status: Ongoing	
Title: SWOG 8104, Treatment of Advanced Seminoma (Stage cII (N ₄) + cIII with Combined Chemotherapy and Radiation Therapy, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, MD, MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the response-rate and survival patterns in patients with advanced seminoma (Stage cII (N₄) + cIII) treated with combined chemotherapy and radiation therapy.

Technical Approach: All patients with histologically proven, Stage cII (N₄) and cIII, advanced, pure or anaplastic testicular seminoma who have had no prior chemotherapy or radiation therapy are eligible. Patients must have no other evidence of malignant disease. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-52		Status: Ongoing	
Title: SWOG 8107, Management of Disseminated Melanoma, Master Protocol, Phase II-III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the effectiveness of cranial irradiation given electively in disseminated melanoma patients with lung and/or liver metastases to prevent or delay the clinical appearance of brain metastases.

Technical Approach: Patients should have histologic proof of melanoma and a negative radiographic study of the brain. Patients must have established disseminated melanoma with lung and/or liver metastases. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-53		Status: Closed	
Title: SWOG 8111, The Treatment of Resected, Poor Prognosis Malignant Melanoma: Stage II: Surgical Excision vs Surgical Excision + Vitamin A vs Surgical Excision + Actinomycin D and DTIC, Phase III.					
Start Date:		Est Comp Date:			
Principal Investigator(s)		Facility:			
Steven A. Madden, M.D., MAJ, MC		DDEAMC			
Dept/Svc:		Associate Investigators:			
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the efficacy of surgical excision plus vitamin A, and surgical excision plus combination chemotherapy (Actinomycin-D and DTIC) in preventing the recurrence of Stage II malignant melanoma by the determination of remission duration or disease-free interval.

Technical Approach: All patients must have a histologically confirmed diagnosis of lymph node melanoma and complete and adequate surgical excision of all residual disease. Patients with completely resected mucosal melanoma or first recurrence will be eligible, but will be stratified separately at the time of registration. All patients must be randomized and treatment begun within six weeks of the lymph node dissection.

Progress: No patients enrolled, study closed to further patient registration.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-54		Status: Ongoing	
Title: SWOG 8122, Combined Modality Treatment of Extensive Small Cell Lung Cancer, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To compare the response rate and duration of a new induction program (multiple alkylating agents plus Vincristine), with emphasis on complete response, to the combination of Vincristine, Adriamycin and Cyclophosphamide in the treatment of extensive small cell lung cancer. To examine the effect of radiation consolidation on relapse in the chest and liver in patients without widespread skeletal disease. To assess qualitative and quantitative toxicity of this combined modality approach. To perform a prospective analysis, by electron microscopy, of the available material for clinicopathologic correlation. To evaluate the effectiveness of a more aggressive radiation therapy approach to clinically evident brain metastases. To evaluate the impact of chest radiation therapy following relapse as to the duration of response and survival. To improve survival and the quality of life in patients with extensive small cell lung cancer.

Technical Approach: All patients with extensive small cell carcinoma of the lung (spread of disease beyond the ipsilateral hemithorax and its regional nodal drainage) are eligible for entry onto this study. Patients must not have had prior treatment with chemotherapy or radiation therapy. Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered on study; taken off 7 Dec 83; expired 31 Dec 83.

Detail Summary Sheet

Date: 1 Oct 84	Prot No.: 84-55	Status: Ongoing
Title: SWOG 8124/5/6, Treatment of Acute Non-Lymphocytic Leukemia with Conventional Induction, Consolidation Chemotherapy: Maintenance with Chemotherapy vs bone Marrow Transplantation Following Total Body Irradiation, Phase III.		
Start Date:	Est Comp Date:	
Principal Investigator(s)	Facility:	
Steven A. Madden, M.D., MAJ, MC	DDEAMC	
Dept/Svc:	Associate Investigators:	
Medicine/Hematology-Oncology		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the complete remission-rate with intensive induction chemotherapy in patients with acute non-lymphocytic leukemia, focusing attention on those patients over 50 years of age.

To compare duration of remission and survival of patients receiving maintenance with or without intensification chemotherapy versus those patients receiving an HLA identical sibling bone marrow transplant while in first remission.

To determine the comparative toxicity of these regimens.

To compare the continuous maintenance therapy and late intensification with late intensification alone.

Evaluate the prognostic significance of any chromosome abnormalities in leukemic cell lines.

Technical Approach: All patients with a diagnosis of acute non-lymphocytic leukemia who have not received prior therapy and who do not have initial CNS leukemia will be eligible for this study. There are no age restrictions; however, patients over the age of 50 will not be considered for bone marrow transplantation.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-56		Status: Ongoing	
Title: SWOG 8200, Evaluation of Vinblastine by Continuous Infusion for Advanced Recurrent Endometrial Carcinoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To evaluate the efficacy of a five day Vinblastine infusion with respect to remission induction, remission duration, and survival duration in patients with advanced, recurrent, or Stages III and IV endometrial carcinoma refractory to prior chemotherapy.

Technical Approach: Patients with pathologically proven adenocarcinoma or adenosquamous carcinoma of the endometrium who have recurrent disease, or Stage III or IV disease no longer treatable with radiation therapy or surgery, are eligible. Patients must not have received prior chemotherapy with vinca alkaloids. Patients may have had previous chemotherapy of other types. Patients must have clinically measurable disease either by radiologic techniques or physical examination. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-57		Status: Ongoing	
Title: SWOG 8208, Trial of Chlorozotocin and 5-FU in Metastatic Islet Cell Carcinoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To study the response of functioning and non-functioning islet cell carcinoma to chlorozotocin (CTZ) and 5-fluorouracil (5-FU). To determine the toxicity of 5-FU and CTZ when given in combination.

Technical Approach: To be eligible for this study, all patients must have biopsy-proven islet cell carcinoma not amenable to further surgical therapy; and a minimum life expectancy of greater than six weeks. All patients must have objectively measurable disease, or a significant biochemical abnormality secondary to endocrine hyperfunction specific for their islet cell tumors. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-58		Status: Closed	
Title: SWOG 8210, A Comparison of Aggressive Radiotherapy + Chemotherapy vs Aggressive Chemotherapy in the Treatment of Limited Carcinoma of the Pancreas, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative QMA Cost:		Periodic Review Results	

Study Objective: To determine whether aggressive therapy with combination radiotherapy/chemotherapy or chemotherapy alone yields superior survival in patients with incurable localized pancreatic cancer.

To compare the toxicities of the two programs.

Technical Approach: Surgical exploration is required to establish truly unresectable localized disease. Patients must have a histological confirmation of adenocarcinoma of the exocrine pancreas. Patients must have a life expectancy of at least 10 weeks. Therapy will follow the schema outlined in the study protocol.

Progress: No patients enrolled, study closed to further patient registration.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-59		Status: Closed	
Title: SWOG 8215, Comparison of Combination Chemotherapy with VP-16 and Cis-Platinum vs BCNU, Thiotepa, Vincristine and Cyclophosphamide in Patients with Small Cell Carcinoma of the Lung Who Have Failed or Relapsed Primary Chemotherapy, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To confirm the efficacy of combination VP-16-213 (VP-16) and Cis-diamminedichloroplatinum (Cis-Platinum) in the treatment of patients with small cell carcinoma of the lung who have failed or relapsed on first-line treatment protocols.

Through a randomized trial, to compare the remission rate, duration of remission, and toxicity between the combination of VP-16 plus Cis-Platinum and the combination of bis-chloroethylnitrosourea (BCNU), triethylenethiophosphoramide (Thiotepa), Vincristine (Oncovin) and Cyclophosphamide (Cytosan) in the same group of patients.

Technical Approach: For inclusion in the study, patients must have a histologically proven diagnosis of small cell carcinoma of the lung and documented relapse or progression following prior therapy. Patients must have had prior chemotherapy. All patients who have relapsed on first-line Southwest Oncology Group protocols for either extensive disease or limited disease, or who have had prior chemotherapy with other induction studies are eligible. Patients may have had prior treatment with any of the agents used in this study, but not with either of the two combinations to be employed. All patients must have a life expectancy of at least six weeks. Therapy will follow the schema outlined in the study protocol.

Progress: No patients enrolled, study closed to further patient registration.

Detail Summary Sheet

Date: 1 Oct 84 Prot No.: 84-60 Status: Ongoing
 Title: SWOG 8219, Evaluation of Combined or Sequential Chemo-Endocrine
 Therapy in Treatment of Advanced Adenocarcinoma of the Prostate, Phase III.

Start Date:		Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the efficacy of the sequential use of endocrine therapy followed at the time of progression by cytotoxic chemotherapy (Adriamycin and cyclophosphamide) versus the combination of endocrine therapy and chemotherapy together in the treatment of advanced adenocarcinoma of the prostate by determination of the response rate, response duration, and duration of survival.

Technical Approach: All patients with histologically proven, asymptomatic or symptomatic Stage D adenocarcinoma of the prostate are eligible. Patients may not have had previous hormonal therapy or chemotherapy. They should have a life expectancy of six weeks or greater. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-61		Status: Ongoing	
Title: SWOG 8228, Correlation Between Progesterone Receptor and Response to Tamoxifen in Patients with Newly Diagnosed Metastatic Breast Disease, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To define the prognostic role of progesterone receptor in patients with newly diagnosed metastatic breast disease by correlating progesterone receptor levels with objective response rates in women treated with Tamoxifen.

Technical Approach: Female patients who have new, metastatic breast carcinoma are eligible for this study. Patients who have received prior hormonal adjuvant therapy are eligible, provided that they have not failed during therapy and the therapy has been stopped for at least three months. Patients must be ER+ in order to be eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84	Prot No.: 84-62	Status: Ongoing
Title: SWOG 8229/30, Combined Modality Therapy for Multiple Myeloma, VMCP-VBAP for Remission Induction Therapy: VMCP + Levamisole vs Sequential Half-Body Radiotherapy + Vincristine-Prednisone for Maintenance or Consolidation. Evaluation of Half-Body Radiotherapy + Vincristine-Prednisone for Patients Who Fail to Achieve Remission Status with Chemotherapy Alone, Phase III.		
Start Date:	Est Comp Date:	
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC	
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the effectiveness of two intermittent pulse schedules of the chemotherapy combination of Vincristine, Melphalan, Cyclophosphamide and Prednisone (VMCP) plus Vincristine, BCNU, Adriamycin and Prednisone (VBAP) (alternating versus syncopated) for the induction of remissions in previously untreated patients with multiple myeloma.

For patients proven to achieve remission (at least 75% tumor regression after induction), to compare the value of 12 months of chemoimmunotherapy maintenance, VMCP + Levamisole, versus a consolidation program consisting of sequential half-body radiotherapy along with Vincristine and Prednisone followed by unmaintained remission.

For patients who only achieve improvement (50%-74% tumor regression) on chemotherapy induction, to determine whether sequential half-body radiotherapy along with Vincristine and Prednisone will increase the remission rate (at least 75% tumor regression).

To determine whether sequential half-body radiotherapy along with Vincristine and Prednisone can serve as an effective form of induction therapy for patients who fail to respond to chemotherapy or suffer early relapse.

Technical Approach: Only previously untreated patients with the diagnosis of multiple myeloma are eligible. This is a first-line study and only patients without prior cytotoxic chemotherapy are eligible.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-63		Status: Ongoing	
Title: SWOG 8231, Chemotherapy of Extragonadal Germinal Cell Neoplasms, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the effectiveness of alternating combination chemotherapy consisting of VBP (Vinblastine, Bleomycin and Cis-Platinum) and EBAP (Bleomycin, Adriamycin, Cis-Platinum and VP-16) in patients with metastatic germinal cell neoplasms arising in extragonadal sites.

To determine the overall toxicity of the alternating combination of VBP and EBAP.

To determine the role of surgical removal of residual disease following this drug combination in partially responding patients.

To compare the response rates observed in this study with those reported by other investigators.

Technical Approach: Patients presenting with a histologically confirmed diagnosis of non-resectable extragonadal germ cell tumors are eligible for this study. All patients should have clearly measurable disease, or an abnormally elevated beta HCG and/or alpha fetoprotein. Patients with extragonadal seminomatous and non-seminomatous neoplasms will be eligible for treatment on this study, but will be analyzed separately. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-64		Status: Ongoing	
Title: SWOG 8235, Evaluation of Continuous Vinblastine in Gastric Carcinoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the response rate, response duration, and duration of survival of gastric carcinoma treated with continuous infusion vinblastine.

To define the qualitative and quantitative toxicities of continuous infusion vinblastine administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of adenocarcinoma of the stomach with gross unresectable residual disease. Both previously treated and untreated patients will be eligible for this study. Patients must have measurable disease. patients must not be receiving concomitant radiation therapy, hormonal therapy, or other chemotherapy while on this protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-65		Status: Ongoing	
Title: SWOG 8244, Clinical Antitumor Activity of Vinblastine Sulfate in Diffuse Mesothelioma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the clinical response rate of five-day continuous infusion vinblastine sulfate in diffuse malignant mesothelioma.

Technical Approach: To be eligible, patients must have a pathologically verified diagnosis of mesothelioma. The mesothelioma may arise either in the thorax or abdomen, but must be of the diffuse malignant type (i.e., not locally resectable by surgery). Patients must have objectively measurable or evaluable lesion(s) excluding CNS metastases and a life expectancy of at least eight weeks. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84	Prot No.: 84-66	Status: Closed
Title: SWOG 8245, Combination Chemotherapy of Unfavorable Histology Non-Hodgkin's Lymphoma with CHOP and CVB (Alternating), Phase II.		
Start Date:	Est Comp Date:	
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: ODEAMC	
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To gain experience with a treatment program utilizing a combination of two alternating non-cross resistant drug regimens in the treatment of "poor prognosis" lymphomas.

To determine an approximate complete remission rate to the Cyclophosphamide, Adriamycin, Vincristine, and Prednisone (CHOP)/Cis-platinum, Vinblastine, and Belomycin (CVB) treatment program prior to initiating a group-wide phase III study utilizing this program.

Technical Approach: Biopsy proven previously untreated patients with Stage II-IV non-Hodgkin's lymphoma, "poor prognosis" histology (diffuse poorly differentiated lymphocytic lymphoma, diffuse histiocytic lymphoma, nodular histiocytic lymphoma, diffuse mixed lymphoma, undifferentiated lymphoma, lymphoblastic lymphoma, and immunoblastic sarcoma) will be eligible for treatment with this regimen. Therapy will follow the schema outlined in the study protocol.

Progress: No patients enrolled, study closed to further patient registration.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-67		Status: Closed	
Title: SWOG 8264, Combination Chemotherapy with m-AMSA, Cis-platinum and MGBG for Refractory Lymphoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine if the three drug combination of methanesulfonamide N-4-(9-acridinyl-amino)-3-methoxyphenyl (m-AMSA), and methyl-glyoxal bis-quanylhydrazone (MGBG) has reasonable activity in patients with refractory unfavorable histology lymphomas; response rate and response duration will be assessed also.

To determine the toxicities of this combination of drugs.

Technical Approach: Eligible patients must have histologically confirmed, unfavorable histology, non-Hodgkin's lymphomas refractory to standard chemotherapy regimens. They must have measurable disease and a life expectancy of at least eight weeks. Therapy will follow the schema outlined in the study protocol.

Progress: No patients enrolled, study closed to further patient registration.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-68		Status: Ongoing	
Title: SWOG 8291, The Intergroup Adult Adjuvant Soft Tissue Sarcoma Study #1. A Randomized Trial of Adjuvant Doxorubicin (Adriamycin NSC#123127) versus Standard Therapy (A Delay of Chemotherapy Until the Time of Possible Relapse)					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: This prospective randomized study is designed to evaluate the efficacy of adjuvant Adriamycin compared to standard treatment (a delay of chemotherapy until the time of demonstrated relapse) in the management of patients with Stages IIB, IIIA-C and tissue sarcoma in terms of local recurrence rate, disease-free interval, and survival.

Technical Approach: For inclusion in this study, patients must have a histopathologically proven diagnosis of soft tissue sarcoma Stages IIB, IIIA-C, and IVA. The tumor may be either previously untreated or a local recurrence.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-69		Status: Ongoing	
Title: SWOG 8292, Treatment for Brain Metastases, Phase III. Intergroup Study (Surgery and/or Radiation Therapy).					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To test whether the addition of surgery before radiation therapy is a significant improvement over radiation therapy alone in the treatment of patients with apparent single brain metastases. Endpoints studied will be:

One year survival rates and median survival times.

Local control rates of brain metastases one month and six months after treatment.

Improvement of neurological deficit as measured by the percentage of patients with improved neurological function.

To evaluate patient refusal with respect to the surgical component.

Technical Approach: All patients having histologically confirmed cancer with evidence of a potentially resectable single intracranial mass lesion as documented by a contrast-enhanced CAT scan are eligible. Only patients with apparently resectable cerebellar or cerebral cortex lesions will be eligible. Patients with bronchogenic carcinoma should have control of the primary tumor and no other metastases prior to admission on this study.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-70		Status: Closed	
Title: SWOG 8305, Chemotherapy of Metastatic Colorectal Carcinoma with 5-FU and Folinic Acid, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To determine the toxicity of 5-fluorouracil (5-FU) and folinic acid (CF) therapy in patients with metastatic colorectal carcinoma.					

To determine the response rate in previously untreated patients receiving 5-FU and folinic acid.

Technical Approach: Patients must have clinically measurable disease to qualify for this study. They must have biopsy-proven adenocarcinoma arising from the colon or rectum. Obstructive lesions in the colon and rectum must have been bypassed or adequately maintained by decompression measures. Therapy will follow the schema outlined in the study protocol.

Progress: No patients enrolled, study closed to further patient registration.

Detail Summary Sheet

Date: 1 Oct 84		Prot No.: 84-71		Status: Ongoing	
Title: SWOG 8311, Combination Chemotherapy with Cis-Platinum, Vinblastine, and Methylglyoxal Bis (Guanyldiazide) (MGBG) in Epidermoid Carcinoma of the Esophagus, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To define the response rate and duration, as well as survival duration, in patients with advanced epidermoid carcinoma of the esophagus when treated with Cis-platinum, Vinblastine and MGBG.

To determine the toxicity of this regimen in the treatment of epidermoid carcinoma of the esophagus.

Technical Approach: All patients must have measurable disease and must have histologically or cytologically confirmed diagnosis of epidermoid carcinoma of the esophagus. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled at DDEAMC.

Detail Summary Sheet

Date: 2 Oct 84 Prot No.: 84-75 Status: Ongoing
 Title: SWOG 8364, Immediate Post-Operative Adjuvant Chemotherapy in Patients with Operable Breast Cancer, Phase II-Pilot.

Start Date:		Est Comp Date:
Principal Investigator(s)		Facility:
Steven A. Madden, M.D., MAJ, MC		DDEAMC
Dept/Svc:		Associate Investigators:
Medicine/Hematology-Oncology		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To assess the toxicity of immediate chemotherapy with Cyclophosphamide, Methotrexate, 5-Fluorouracil, Vincristine and Prednisone beginning at the time of surgery in patients with Stage II carcinoma of the breast.

Technical Approach: All female patients with biopsy proven disease of breast cancer (may be frozen section) which appears to be operable. Patients with clinical T₁-T₂N₀-1 are eligible. Chemotherapy must be started within 24 hours of modified radical mastectomy of lumpectomy with axillary dissection. Patients having needle biopsy, incisional or excisional biopsy prior to more definitive surgery ("two-step procedure") must have the definitive surgery within 48 hours of biopsy and chemotherapy within 24 hours of surgery to minimize any lag time between manipulation of tumor and administration of cytotoxic agents. Receptor studies should be performed at the time of biopsy or definitive surgery. Patients who are found to have metastatic disease or T₁N₀ disease after pathologic staging (permanent sections) will be removed from the study and will receive no more than the first course of chemotherapy. Therapy will follow the schema outlined in the study protocol.

Progress: Study approved locally in Sep, not yet implemented.

Detail Summary Sheet

Date: 2 Oct 84		Prot No.: 84-76		Status: Ongoing	
Title: SWOG 8393, National Intergroup Protocol for Intermediate Thickness Melanoma 1.0 to 4.0 MM - Evaluation of Optimal Surgical Margins (2vs4 cm) Around the Primary Melanoma and Evaluation of Elective Regional Lymph Node Dissection.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: Determine whether it is necessary to perform a wide local excision for local control of primary melanomas measuring 1 to 4 mm in thickness. Determine whether the timing of surgical lymphadenectomy for regional node metastatic disease influences survival rates in those patients selected by prognostic factors analysis who are at risk for micrometastases confined to their lymph nodes.

Technical Approach: Eligible patients with melanomas on the trunk or proximal extremity will be prospectively randomized into 2 groups: 1) standard wide excision of at least 4 cm of healthy tissue from the margin of the primary or the scar resulting from excisional biopsy of the primary lesion, 2) an excision with margins 2 cm from the edge of the primary lesion or the biopsy scar. Eligible patients with melanomas on the head, neck and distal extremity will all have a definitive excision with a 2 cm margin of skin.

Progress: Study approved locally in Sep 84, not yet implemented.

Detail Summary Sheet

Date: 2 Oct 84		Prot No.: 84-77		Status: Ongoing	
Title: SWOG 8293, Intergroup Phase III Protocol for the Management of Locally or Regionally Recurrent but Surgically Resectable Breast Cancer.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine whether the application of aggressive chemotherapy and radiation therapy as single modalities or in sequential combination in patients with technically resectable locally or regionally recurrent carcinoma of the breast will result in increased survival and/or prolonged disease-free interval.

Technical Approach: Patients allocated to Schema C will be randomized at the time of registration to one of the 3 treatment plans: Chemotherapy followed by radiation therapy (Treatment Arm I), chemotherapy followed by observation (Treatment Arm II), or radiation therapy followed by observation (Treatment Arm III).

Progress: Study approved locally in Sep 84, not yet implemented.

Detail Summary Sheet

Date: 2 Oct 84		Prot No.: 84-78		Status: Ongoing	
Title: SWOG 8300, Treatment of Limited Non-Small Cell Lung Cancer: Radiation vs Radiation Plus Chemotherapy (FOMi/CAP), Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To compare combination chemotherapy (FOMi/CAP) plus radiotherapy to radiotherapy alone for patients with limited, non-small cell lung cancer (NSCLC) in a randomized study with stratification for known important prognostic factors with regard to response rate, response duration and survival duration. 2) To determine the toxicity of radiotherapy plus FOMi/CAP relative to radiotherapy alone for patients with limited NSCLC. 3) To evaluate the responsiveness of smaller tumor burdens to FOMi/CAP (i.e., less than metastatic disease). 4) To determine the pattern of relapsing disease in each treatment arm and in subgroups of patients determined by histology and response to FOMi/CAP. 5) To determine if prophylactic brain irradiation will decrease the chances for brain metastases and influence toxicity or survival.

Technical Approach: All patients must have a histologic or cytologic diagnosis of non-small cell carcinoma of the lung (squamous, large cell undifferentiated or adenocarcinoma). Cytology should be confirmed at least twice. Patients must have limited disease. Disease must be confined to a single hemithorax, and/or the ipsilateral hilar lymph nodes, and/or the mediastinum, and/or the ipsilateral supraclavicular lymph nodes. In addition, the patient's disease must be encompassable in a single radiation port. Patients with pleural effusion are not eligible for the study if the effusion is considered to be malignant. A radiation oncology consult is required prior to patient registration. Patients must have unresectable disease (Stage II or IV).

Progress: Study approved locally in Sep 84, not yet implemented.

Detail Summary Sheet

Date: 2 Oct 84		Prot No.: 84-79		Status: Ongoing	
Title: SWOG 8308, Combination of Cis-Platinum and Dichloromethotrexate in Patients with Advanced Bladder Cancer, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To obtain data regarding the activity and toxicity of combination cis-platinum and dichloromethotrexate in patients with objectively measurable metastatic transitional cell carcinoma of the bladder who have good renal function and who have not previously received chemotherapy. 2) To investigate the single agent activity and toxicity of dichloromethotrexate in previously untreated patients with impaired renal function.

Technical Approach: All patients must have a histologically confirmed diagnosis of metastatic transitional cell carcinoma of the urothelium. Only patients without prior systemic chemotherapy (prior intravesical therapy allowable) are eligible for this study. Patients with prior radiotherapy are eligible if the disease has progressed, if at least six weeks have elapsed since completion of the radiotherapy (non-cranial) and if measurable sites of disease exist outside of the previous radiation field. Patients must have a performance status of 3 or better (Karnofsky Scale, >50). All patients must have at least one bidimensional (perpendicular diameters) objectively measurable site of disease.

Progress: Study approved locally Sep 84, not yet implemented.

Detail Summary Sheet

Date: 2 Oct 84		Prot No.: 84-80		Status: Ongoing	
Title: SWOG 8312, Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in combination as Second-Line Endocrine Therapy of Estrogen Receptor Positive Metastatic Breast Cancer, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To determine whether combination hormonal therapy with Aminoglutethimide and Hydrocortisone (AH) plus Megestrol Acetate (M), agents thought to have different mechanisms of action, offers an improved response rate with prolonged response duration and increased patient survival over the sequential use of each agent in Estrogen Receptor (ER) positive patients who have progressed after responding to primary hormonal treatment with Tamoxifen. 2) To assess the relative toxicities of Megestrol acetate and medical adrenalectomy. 3) To assess the value of progesterone receptor (PgR) in predicting subsequent responses to a variety of hormonal therapies.

Technical Approach: Post-menopausal female patients with progressive, measurable metastatic breast carcinoma are eligible for this study. The post-menopausal state is defined as 1) physiologic menopause at least one year prior to entry or 2) previous surgical castration for reasons unrelated to breast cancer. Patients with previous hysterectomy should have post-menopausal levels of FSH and LH.

Progress: Study approved locally in Sep 84, not yet implemented.

Detail Summary Sheet

Date: 2 Oct 84		Prot No.: 84-81		Status: Ongoing	
Title: SWOG 8313, Multiple Drug Adjuvant Chemotherapy for Patients with ER Negative Stage II Carcinoma of Breast, Phase III.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To compare through a randomized prospective study, the recurrence rates and disease-free intervals (DFI) for post-operative axillary node positive estrogen receptor negative (ER-) breast cancer patients given adjuvant therapy with either short term intense chemotherapy (FAC-M) or one year standard chemotherapy (CMFVP). 2) To compare the effect of these two adjuvant therapies on survival. 3) To compare the relative toxicity of the two therapies.

Technical Approach: All patients must have histologically proven breast carcinoma with metastases to one or more axillary nodes (Stage II or III T_{1-3a}N₁) to be eligible. The tumor must be classified according to TNM Classification. The primary tumor must be movable in relation to the anterior chest wall and must not be involved with skin ulcerations. Axillary nodes must be movable in relation to the chest walls and vessels, and there can be no edema of the arm pre-operatively.

Progress: Study approved locally in Sep 84, not yet implemented.

Detail Summary Sheet

Date: 2 Oct 84		Prot No.: 84-82		Status: Ongoing	
Title: SWOG 8325, Combination Chemotherapy with O,P'-DDD and Cis-Platinum in Metastatic Adrenal Carcinoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To study the responsiveness of adrenocortical carcinoma to combination chemotherapy consisting of Cis-Platinum (DDP) and Mitotane (O,P'-DDD). 2) To study the prognostic features of patients with metastatic and/or unresectable adrenal carcinoma receiving chemotherapy. 3) To document the toxicity of chemotherapy in this group of patients.

Technical Approach: Patients with metastatic or residual adrenocortical carcinoma in whom further surgical removal of disease is not possible will be eligible. All patients should have an expected life span of ≥ 4 weeks. Objectively measurable disease on physical examination or x-ray studies, or the presence of a biochemical abnormality specific for that patient's tumor, e.g., elevated urinary 17-keto- or 17 hydroxycorticoids, must be present.

Progress: Study approved locally in Sep 84, not yet implemented.

Detail Summary Sheet

Date: 2 Oct 84		Prot No.: 84-83		Status: Ongoing	
Title: SWOG 8386, Evaluation of Fludarabine Phosphate in Colorectal Carcinoma, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To determine the antitumor activity of Fludarabine Phosphate in patients with colorectal carcinoma by determination of the response-rate and remission duration. 2) To further define the qualitative and quantative toxicities of this drug in a Phase II study.

Technical Approach: Patients must have biopsy proven adenocarcinoma arising from the colon or rectum. Patients must have clinically measurable recurrent or disseminated disease to qualify for the study. Clearly defined lesions on liver scans or roentgenograms are acceptable. Patients must have a life expectancy of at least ten weeks and a performance status of 0-2 by Southwest Oncology Group criteria.

Progress: Study approved locally in Sep 84, not yet implemented.

Detail Summary Sheet

Date: 2 Oct 84		Prot No.: 84-84		Status: Ongoing	
Title: Combination Chemotherapy of Intermediate and High Grade Non-Hodgkin's Lymphoma with m-BASOD, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., M.A., MC			Facility: DDEAMC		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To determine an approximate complete remission rate and remission duration for the treatment program of cyclophosphamide, doxorubicin, vincristine, dexamethasone, and bleomycin with intervening moderate dose methotrexate and leukovorin rescue (m-BACOD), in patients with intermediate and high grade non-Hodgkin's lymphoma. 2) To assess the feasibility of using this regimen in the Southwest Oncology Group with the intent of using m-BACOD in a future Phase III trial.

Technical Approach: Patients must have biopsy proven Stage II-IV non-Hodgkin's lymphoma, intermediate or high-grade histology. Therapy will follow the schema outlined in the study protocol.

Progress: Study approved locally in Sep 84, not yet implemented.

Detail Summary Sheet

Date: 2 Oct 84 Prot No.: 84-85 Status: Ongoing
 Title: SWOG 8411, Evaluation of DTIC in Metastatic Carcinoid, Phase II.

Start Date:		Est Comp Date:
Principal Investigator(s)		Facility:
Steven A. Madden, M.D., MAJ, MC		DDEAMC
Dept/Svc:		Associate Investigators:
Medicine/Hematology-Oncology		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To determine the effectiveness of dimethyl triazeno imidazole carboxamide (DTIC) in the treatment of metastatic carcinoid. 2) To determine the survival of patients with metastatic carcinoid receiving DTIC.

Technical Approach: Patients must have biopsy proven carcinoid tumor not amenable to further surgical therapy. Patients must have a minimum life expectancy of 6 weeks. All patients must have objectively measurable disease either as a measurable lesion, or significant biochemical abnormality specific for their tumor (elevated urinary 5-HIAA documented on 2 separate occasions).

Progress: Study approved locally in Sep 84, not yet implemented.

Detail Summary Sheet

Date: 2 Oct 84		Prot No.: 84-86		Status: Ongoing	
Title: SWOG 8415, Evaluation of Tamoxifen in Unresectable and Refractory Meningiomas, Phase II.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the antitumor activity of Tamoxifen in meningiomas not amenable to surgery or radiotherapy. To estimate the response rate and response duration experienced by these patients.

Technical Approach: All patients must have a biopsy proven diagnosis of benign meningioma. All patients must have measurable disease by CT scan or NMR scan. Patients must be unresectable for medical or technical reasons, or have measurable residual disease.

Progress: Study approved locally in Sep 84, not yet implemented.

Detail Summary Sheet

Date: 2 Oct 84 Prot No.: 84-87 Status: Ongoing
 Title: SWOG 8490, Phse II Study of PAC (Cis-Platinum, Adriamycin, and Cyclophosphamide) in Treatment of Invasive Thymoma, Intergroup Study.

Start Date:	Est Comp Date:	
Principal Investigator(s)	Facility:	
Steven A. Madden, M.D., MAJ, MC	DDEAMC	
Dept/Svc:	Associate Investigators:	
Medicine/Hematology-Oncology		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the objective response rate in extensive and limited invasive thymoma treated with PAC (Cis-Platinum, Adriamycin, Cyclophosphamide). To determine the duration of remission of patients with limited invasive thymoma treated with split course radiotherapy plus PAC and in patients with extensive disease treated with PAC alone.

Technical Approach: All patients must meet the following criteria: Locally invasive, recurrent or metastatic thymoma; histologic confirmation by Group pathologist; at least one bidimensional measureable lesion; serum creatinine of 1.5 mg/dl or less, or creatinine clearance of 70 ml/minute or better; serum bilirubin of 2.0 mg/dl or less; no prior chemotherapy with alkylating agents, Adriamycin or Cis-Platinum; no prior history of congestive heart failure; performance status 40% or better (Karnofsky); WBC $\geq 4,000/\mu\text{l}$, platelet count $\geq 125,000/\mu\text{l}$.

Progress: Study approved locally in Sep 84, not yet implemented.

Detail Summary Sheet

Date: 20 Jul 84 Prot No.: 82-49 Status: Completed
 Title: The Use of Social Support by Rheumatoid Arthritic Women from Different Cultural/Ethnic Backgrounds.

Start Date: Sep 82		Est Comp Date:
Principal Investigator(s) Vickie A. Lambert, RN, D.N.Sc. Clinton E. Lambert, Jr., CPT, ANC		Facility: Medical College of Georgia DDEAMC
Dept/Svc: Nursing		Associate Investigators:
Key Words: Social support Rheumatoid arthritic Women		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jul 84 Review Results Completed

Study Objective: To identify differences in the nature of the relationships between three types of social support and psychological well-being in rheumatoid arthritic women from three different cultural/ethnic backgrounds.

Technical Approach: Administration of three structured questionnaires by way of interview. Interview to be conducted while subject waiting for scheduled clinic appointment with rheumatologist.

Number of subjects enrolled to date: 60.

Number of subjects enrolled for reporting period: 2.

Progress: No significant differences were found between the social support characteristics or between psychological well-being for the two groups. Significant correlations were shown between each of the social support characteristics and psychological well-being for Caucasian women, but not for Black women. No combination of social support characteristics was found to be any better than any other for predicting psychological well-being in either group. The findings suggest that factors other than social support influence psychological well-being in women with rheumatoid arthritis and that the evaluative instruments used were not sufficiently sensitive.

Detail Summary Sheet

Date: 10 Oct 84		Prot No.: 83-26		Status: Ongoing	
Title: Sixteen Personality Factor Profile Responses and Demographic Data Used as Predictors of Final Student Rankings in a Practical Nurse Course.					
Start Date: Jul 83			Est Comp Date:		
Principal Investigator(s) Joseph M. Mucha, Jr., MAJ, ANC			Facility: DDEAMC		
Dept/Svc: Nursing			Associate Investigators:		
Key Words: Predictors of Final Student Rankings					
Accumulative MEDCASE		Est Accumulative		Periodic Jul 84	
Cost:		OMA Cost:		Review Results Continue	
Study Objective: To utilize a demographic and personality questionnaire to identify those students who will be successful in completing the Practical Nurse Course.					

Technical Approach: Practical Nurse Course students did a completion
of the Sixteen Personality Factor Profile and investigator-prepared
Demographic Data questionnaires.

Subjects enrolled to date: 70
Subjects enrolled for reporting period: 45

Progress: Plan to administer questionnaires to one more class in April 1985,
then answers will be compared to the other two classes.

Detail Summary Sheet

Date: 20 Jul 84 Prot No.: 83-28 Status: Completed
 Title: Family Childrearing Styles, Child Medical Fears and Maternal Presence
 as Predictors of Young Children's Response to Pain.

Start Date: Aug 83		Est Comp Date: May 84
Principal Investigator(s) Marion E. Broome, RN, MN, Doctoral Student Cynthia Moen-Noqueras, MAJ, ANC		Facility: DDEAMC
Dept/Svc: Nursing Pediatrics		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jul 84 Review Results Completed

Study Objective: To gather data on the relationship between a parent's presence, his/her childraising practices, the child's sensitivity to medical events and how the child responds to pain produced by an injection.

Technical Approach: Data was collected at five different points during the pre-school screening process. Consent was obtained prior to data collection for each parent/child pair. Data collection involved questionnaires filled out by the parents, interviews with the child and observation of both child and parent behavior during the injection.

Number of subjects enrolled to date: 138.

Progress: Parents filled out a questionnaire on their childrearing practices and the children were asked to describe how afraid they were of selected medical experiences. The parents were also assigned to groups in which they were either present or absent while their children received the immunization and the children's behavior was observed.

Detail Summary Sheet

Date: 22 Jun 84	Prot No.: 83-38	Status: Completed
Title: A Measure of Satisfaction in Childbirth: The Degree of Women's Fulfillment of Childbearing Expectations.		
Start Date: Oct 83	Est Comp Date: Dec 83	
Principal Investigator(s) Paulette A. Cooke, MAJ, ANC	Facility: DDEAMC	
Dept/Svc: Nursing	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To operationalize the concept of satisfaction as it pertains to the labor and delivery experience. The goal is to test a tool which purports to measure the degree of satisfaction with the labor and delivery experience.

Technical Approach: Sample/Population Studied: Data were collected on a convenient sample of 50 postpartum women. The women: (a) spoke and understood English, (b) had experienced a vaginal delivery within the past 6 to 18 hours, (c) delivered a normal, full-term infant (5 lbs, 8 oz or more) with an Apgar score at five minutes of 8 or more, (d) had no medical or obstetrical complications during labor and delivery, and (e) had been in the labor suite for at least one hour.

Method of Data Collection: The reliability of the Cooke Satisfaction Scale was obtained in two phases. Phase I: the establishment of content validity via a panel of experts. Phase II: testing if the Cooke Satisfaction Scale on the sample of postpartum women.

Method of Data Analysis: Reliability and validity estimates for the Cooke Satisfaction Scale were obtained as well as the degree of satisfaction with the childbirth experience. The Marut and Mercer Attitude Scale was used in the establishment of convergent and divergent construct validity.

Progress: Completed.

Findings: The results of content validity indicated that all the items were considered relevant for the measure of satisfaction with the childbirth experience. The reliability coefficient (Cronback's Alpha) for the Cooke Satisfaction Scale was .89. The correlation for the Cooke Satisfaction Scale (Part A) and the Marut and Mercer Scale for convergent construct validity was .53. The correlation for the Cooke Satisfaction Scale (Part A - Part B) with the Marut and Mercer Scale for divergent construct validity was .15. On the basis of reliability and validity coefficients obtained, it was concluded that the Cooke Satisfaction Scale is a useful tool for the measurement of satisfaction in childbearing women.

Detail Summary Sheet

Date: 30 Sep 84		Prot No.: 84-3		Status: Ongoing	
Title: The Effects of Heated and Humidified Anesthetic Gases on Core Body Temperature.					
Start Date: Nov 83			Est Comp Date: Nov 84		
Principal Investigator(s) Christopher A. Krupp, CPT, ANC Eugene J. Murdock, Jr., CPT, ANC Cheryl S. Beaubé, CPT, ANC Robert Marchi, CPT, ANC			Facility: DDEAMC		
Dept/Svc: Nursing/Anesthesiology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the change in core body temperature in those patients receiving heated/humidified gases versus those patients receiving the common method of gas delivery-ambient temperature/dry.

Technical Approach:

1) Experimental design: a post-test only, equivalent - group experimental design will be used in this study. Random selection of the research population will be carried out using a table of random numbers with subjects being divided into an experimental and a control group. Following data collection, a statistical analysis using the student test will be performed. The results of our analysis will compare the independent variables (heated and humidified anesthetic gases) and the dependent variables (core body temperature) of the two groups.

2) Manpower: Investigators listed above.

3) Experimental subjects: 19
Control subjects: 19

4) Significant adverse reactions: None.

5) Funding: None.

Progress: Data collection terminated due to deadline. Results and conclusions are in process of being tabulated. Results will be forwarded in Nov 84.

Detail Summary Sheet

Date: 5 Oct 84		Prot No.: 84-73		Status: Ongoing	
Title: Transition into Military Nursing: An Evaluation of A Preceptorship Program.					
Start Date: Sep 84			Est Comp Date: Oct 85		
Principal Investigator(s) Bruce C. Allanach, LTC, ANC			Facility: DDEAMC		
Dept/Svc: Nursing			Associate Investigators: Bonnie Jennings, MAJ(P), ANC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: Examine those factors which facilitate the integration of new ANC officers into a hospital nursing milieu. Determine whether locus of control, as well as affective states of anxiety, hostility, and depression are prime factors in the integration of new ANC officers. Develop a protocol which examines whether there are any differences among nurse preceptees within the same preceptorship program who are judged to be a success. The literature reflects that participants in such programs evaluate the programs as successful. Locus of control and multiple affective states may underscore differences in participants evaluation of a program as successful. A preceptorship program is geared to ease transition phenomenal among new nurses who are prone to affective states associated with change such as anxiety, hostility, and depression.

Technical Approach: The data collection for each preceptee occurs over a period of 26 weeks. The plan is evaluation research using a time-series design. The effects of the program will be examined against the goals through a series of measurements during week 1, 4, 8, 9, 13, and 24 after arrival at DDEAMC. These points of time include before the program begins, during the program, and after the program ends. The principal investigator administers the tools. A total of twelve (12) new ANC officers met the qualifications of the Preceptorship Program and were enrolled in the program in September 1984.

Progress: Approval of proposal was made in July 1984 with the initial group of 12 new nurses entering the program in September 1984. Data collection is estimated to take one year before a convenience sample size of 50 is obtained. Project will continue at least through Fall 1985.

Detail Summary Sheet

Date: 2 Oct 84	Prot No.: 84-74	Status: Ongoing
Title: Religiosity, Anxiety, and Patient Satisfaction in a Group of Seriously Ill Cancer Patients.		
Start Date: Oct 84	Est Comp Date: Jan 85	
Principal Investigator(s) Rosa Maria Baunchalk, CPT, ANC	Facility: DDEAMC	
Dept/Svc: Medicine/Oncology/Nursing	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: An attempt to demonstrate the significance of religiosity in a group of seriously ill cancer patients. The relationships between religiosity, anxiety, and patient satisfaction with nursing care will be examined.

Technical Approach: A convenience sample of 20-30 oncology inpatients will be selected for this study. The demographic and research data obtained will be entered into a computer with the subject's identifying code number only. Three instruments will be used: The Religious Belief Questionnaire, the state anxiety scale from the State-Trait Anxiety Inventory, and the Patient Satisfaction Instrument.

Progress: Study approved locally Sep 84, not yet implemented.

Detail Summary Sheet

Date: 5 Oct 84 Prot No.: 84-49 Status: Ongoing
 Title: The Role of Stress in the Etiology of Obesity.

Start Date: Jun 84		Est Comp Date:
Principal Investigator(s) Janet G. Tingle, CPT, AMSC		Facility: DDEAMC
Dept/Svc: Nutrition Care Division		Associate Investigators: Katie Boyd, LTC, AMSC
Key Words: Stress/Trauma/Obesity		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To investigate the possible role of stress or trauma in the development of obesity.

Technical Approach: a. Two separate studies are being conducted. In study one, post multiple fracture patients are contacted through the mail and asked to complete a questionnaire dealing with stress, eating habits, and weight control. In the second study, known obese and "ideal" weight males and females between the ages of 30 and 50 are interviewed through a questionnaire and a personal interview about stress, eating responses, development of a weight problem, etc. Skinfold measurements are done on each of these subjects.

b. All personal interviews and skinfold measurements have been completed by the principal investigator with the assistance of four of the dietitians from the Nutrition Care Division.

c. Thirty-six questionnaires were originally sent out to post multiple fracture patients. Ten of these questionnaires have been returned. In study two, 187 subjects have been interviewed.

Progress: Accomplishments up to this point include development of the questionnaires, locating subjects for the study, and obtaining completed questionnaires. Analysis of the data collected in study two is beginning as sufficient subjects have been interviewed for this study. Additional subjects for study one are being located.

Detail Summary Sheet

Date: 25 Jun 84 Prot No.: 81-22 Status: Terminated
 Title: Immunopathological Identification (Classification) of Lymphomas.

Start Date: Nov 81		Est Comp Date:
Principal Investigator(s) Mark C. Anderson, D.O., MAJ, MC		Facility: DDEAMC
Dept/Svc: Pathology		Associate Investigators: Janet Lamke, MT, ASCP, DAC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To develop an aid in the diagnosis and evaluation of human lymphomas for routine use on biopsy specimens.

Technical Approach: Old cases, using paraffin sections, will be studied first to evaluate the immunofluorescent technique. From all biopsy lymphnode material, a sampling will be snap-frozen and stored at -70°C. Immunofluorescent testing with various antisera will be performed on each biopsy and results recorded by technologist and analyzed by pathologist. Correlation of other histological procedures and data and resulting diagnosis is the responsibility of the pathologist.

Progress: No activity during FY 84, PI has PCS'd, study is terminated.

Detail Summary Sheet

Date: 15 Oct 84		Prot No.: 81-32		Status: Terminated	
Title: A Comparative Study of Immunofluorescence in Fresh Frozen and Paraffin-Embedded Skin Tissue.					
Start Date: Jun 81			Est Comp Date:		
Principal Investigator(s)			Facility:		
Janet H. Lamke, MT, DAC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Pathology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To confirm the results of previous investigators, to develop a reliable technique for the processing of paraffin-embedded skin tissue, and to investigate the demonstration of complement deposits in paraffin-embedded skin tissue of patients with certain auto-immune skin disorders.

Technical Approach: In patients suspected of having auto-immune disease, biopsies are routinely taken for immunofluorescent studies and H E sections. Some of the remaining paraffin-embedded tissue will be processed according to various methods that we establish and stained by immunofluorescence antisera.

Progress: Study is terminated due to lack of appropriate samples.

Detail Summary Sheet

Date: 10 Oct 84 Prot No.: 84-4 Status: Ongoing
 Title: Metastatic Adenocarcinoma of Unknown Primary Site.

Start Date: Nov 83		Est Comp Date: May 85
Principal Investigator(s) Ricky Reaves, M.D., CPT, MC Phyllis Brewer, DAC Jack A. Horner, DAC		Facility: DDEAMC
Dept/Svc: Pathology Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether or not the primary site of a metastatic adenocarcinoma of unknown origin can be determined with a high degree of accuracy.

Technical Approach: (1) Gathering cases where primary tumor site is unequivocal.

(2) Manpower: Three.

(3) Morphometric measurements will be made on tumors from known primary sites (adenocarcinomas only) to determine if a statistically significance difference in microvillus size can be assigned to the various primary organs.

Progress: For reasons relating to increased workload and equipment downtime, little progress has been made in the reporting period. Currently, cases are still being gathered. Also an unanticipated problem must be resolved, i.e., most cases of tumors from known primaries (e.g., lung, breast, colon, stomach) are resected and placed in formalin. Biopsies of tumors with unknown primaries are often placed in gluteraldehyde. A small group of cases will be processed both ways to determine if significant site changes occur.

Detail Summary Sheet

Date: 5 Sep 84 Prot No.: 83-31 Status: Completed
 Title: Patient Admission Anxiety and Its Effect on Length of Stay.

Start Date: Sep 83		Est Comp Date: Dec 83
Principal Investigator(s) James A. Halvorson, CPT, MSC		Facility: DDEAMC
Dept/Svc: Patient Administration Division		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine a relation, if any, between admission anxiety and length of stay (LOS).

Technical Approach: Volunteer patients complete the State Trait Anxiety Inventory (STAI). Length of stay is determined upon discharge. Results are compared with the average LOS for that particular diagnosis in DDEAMC during 1982.

150 patients enrolled during FY 83.
 10 patients enrolled during FY 84.

Progress: This study evaluated the anxiety level exhibited by patients at the time of admission to the hospital and attempted to find a correlation, if any, between that level of anxiety as expressed on the State-Trait Anxiety Inventory and the length of stay experienced by that patient. The average lengths of stay were determined for all diagnostic categories of patients admitted during the previous year (1982). Subjects were given the STAI during administrative processing in the Admissions Office. The average length of stay for that diagnostic code, the current length of stay, scores on the STAI, and self-reported measure of anxiety were variables used in data manipulation. With 160 volunteer subjects participating, none of the variables were shown to be correlated significantly to another. The outcome raises doubts about the leverage of anxiety as a determinant of hospital stay.

Manuscript, title same as above, submitted to Journal of Psychosomatic Medicine.

Detail Summary Sheet

Date: 16 Oct 84 Prot No.: 82-55 Status: Terminated
 Title: Relative Accuracy of Adolescent- and Adult-Normed MMPI Profiles in
 Young Enlisted Military Personnel.

Start Date: Oct 82		Est Comp Date:
Principal Investigator(s) Jerry R. DeVore, PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc: Psychiatry and Neurology/Psychology		Associate Investigators: Glenn Walters, PhD, CPT, MSC
Key Words:		Ft Levenworth Disciplinary Barracks
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 83 Review Results Continue

Study Objective: To investigate the relative accuracy of behavioral narratives generated by adolescent- and adult-normed profiles.

Technical Approach: Three hypotheses will be tested in this study: 1) behavioral narratives based on adolescent MMPI norms will be rated as reasonably accurate by a group of interviewers familiar with the behavior of the subjects under investigation (i.e., active duty enlisted personnel between the ages of 18 and 21); 2) behavioral narratives based on adolescent MMPI norms will be judged as more accurate than narratives generated by K-corrected or non-K-corrected adult norms; 3) various patient characteristics (e.g., race, sex, education) will not have a major impact on the results.

No subjects enrolled to date or during reporting period.

Progress: A program for computer printing interpretive paragraphs was developed by the principal investigator on his privately owned personal computer. However, the project was terminated this year due to unforeseen increases in the clinical duties of the principal investigator and the clinical duties of the staff who were to rate the accuracy of the interpretations. The increased duties were not foreseen because of unanticipated non-replacement of staff personnel losses. At this point, future replacement is still indefinite. The principal investigator hopes that whenever there is sufficient staff, he will reapply to conduct this investigation.

Detail Summary Sheet

Date: 5 Oct 84	Prot No.: 84-1	Status: Ongoing
Title: The DDEAMC Alcohol Residential Treatment Facility Patient Outcome Study.		
Start Date: Oct 83	Est Comp Date:	
Principal Investigator(s) William F. Shivers, Jr., M.D., LTC, MC Thomas W. Hester, M.D., MAJ, MC Peter S. Jensen, M.D., MAJ, MC Daniel Hendricks, CPT, MSC	Facility: DDEAMC	
Dept/Svc: Psychiatry and Neurology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To better understand alcoholism and its treatment by assessing some of its biological, psychological, and social concomitants, and determining their diagnostic and prognostic validity.

Technical Approach:

1. Summary of Experimental Design: This study is prospective in design. Measures of the above mentioned variables will be taken prior to, and upon completion of, treatment. Additionally, follow-up questionnaires are to be completed by the patient, spouse, and patient's commander at intervals of three, six, nine, twelve, and twenty-four months after discharge. Relationships will be measured using analysis of variance and analysis of covariance procedures.
2. Manpower: Personnel required to gather, collate, and interpret the data are, at a minimum, one 91G Behavioral Science Specialist, one Medical Records Technician, and one Clinical Psychologist.
3. Funding: Not applicable.
4. Number of subjects enrolled to date: 137
5. Number of subjects enrolled during reporting period: 137
6. Adverse reactions: None.

Progress: Pre-treatment, discharge, and partial follow-up data have been collected on 137 subjects. With the recent acquisition of a staff Clinical Psychologist, we have begun to analyze the data for the first 137 subjects. Preliminary reports on the data from these subjects will include a demographic definition of the treatment population, and assessment of the validity of various "biological markers" previously reported as concomitants of alcoholism.

Detail Summary Sheet

Date: 10 Oct 84		Prot No.: 84-24		Status: Terminated	
Title: Validation of American Critical Care Graded Neurologic Examination Scale.					
Start Date: Feb 84			Est Comp Date:		
Principal Investigator(s)			Facility:		
Robert J. Adams, M.D.			DDEAMC		
Charles R. Wolf, III, M.D., MAJ, MC			Associate Investigators:		
Dept/Svc:					
Psychiatry-Neurology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine if the designed graded scale accurately assesses the severity and change of a stroke patient's neurologic condition as compared to a qualitative assessment provided by an experienced neurologist.

Technical Approach: There have been no subjects enrolled.

Objective: Patients who meet the study criteria have been available in insufficient numbers to adequately contribute to the project. This study should be terminated.

Detail Summary Sheet

Date: 10 Oct 84		Prot No.: 84-28		Status: Ongoing	
Title: Reliability and Agreement of Reports of Children's Symptoms.					
Start Date: Apr 84			Est Comp Date:		
Principal Investigator(s)			Facility:		
Peter S. Jensen, MD, MAJ, MC			DDEAMC		
Michael W. Bain, MD, LTC, MC			Associate Investigators:		
Dept/Svc:					
Psychiatry-Neurology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To examine the effects of parent and child gender and parental depressive symptoms on the reliability and agreement of children's and parents' reports of children's symptoms and behavior problems.

Technical Approach: (1) One hundred 2-parent families will be selected from on-post housing lists to participate in a study of children's depressive symptoms. To be eligible, families must have a child age 8-12. Also, 100 parents and children who are referred to the Child, Adolescent and Family Psychiatry Service at DDEAMC will also participate in the study. Both groups of families will be compared vis a vis then reports of children's depressive symptoms (Scales used are well-standardized instruments including the Child Behavior Checklist, the Child Depression Inventory, and the Beck Depression Inventory). Reliability and agreement between mother's, father's and children's reports will be analyzed to determine how these indices are affected by sex of parent and child, and depression in the parent.

- (2) Manpower required is limited to the two current principal investigators.
- (3) Funding required is to provide computer support and statistical analysis.
- (4) No subjects are yet enrolled, pending approval of use of post housing lists; enrollment expected within the next quarter.
- (5) No adverse reactions.

Progress: Expect approval of use of housing lists and contact of post families within this next quarter.

Detail Summary Sheet

Date: 5 Oct 84		Prot No.: 84-43		Status: Ongoing	
Title: Participation in Restandardization of Minnesota Multiphasic Personality Inventory.					
Start Date: May 84			Est Comp Date: Fall 85		
Principal Investigator(s) Frank H. Rath, Jr., PhD., LTC, MSC Jerry R. DeVore, PhD., CPT, MSC			Facility: DDEAMC		
Dept/Svc: Psychology Service Community Mental Health Service			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: The Minnesota Multiphasic Personality Inventory (MMPI) is the most frequently used personality assessment procedure for clinical purposes in the US Army as well as in general health care practice in the US. Developed in the late 1930's, early 1940's it has long been recognized that cultural and demographic changes have altered the normative basis of the MMPI and have made the range of content area covered less comprehensive than desirable. It is necessary to establish new norms for the MMPI for the currently used clinical scales and to develop norms for new clinical scales to be developed (e.g., alcohol and drug abuse, type A behavior, treatment compliance, etc.) with the addition of new content items. It is highly desirable that active duty Army personnel be part of the restandardization sample, as the restandardized MMPI will be used frequently with Army personnel.

Technical Approach: a. Experimental design. This research is not an experiment. It is a population characteristics study. A new form of the MMPI which included all of the old items and over 150 new items was administered to a population of active duty soldiers, most of whom were enlisted trainees in Signal MOS AIT courses.

b. Manpower: The principal investigators changed during the course of the study. Jerry R. DeVore, PhD, CPT, MSC; Amy Flowers, PhD, CPT, MSC; and Frank H. Rath, Jr., PhD, LTC, MSC are now the principal investigators. James N. Butcher, PhD, University of Minnesota, is an associate investigator. Additionally, James Warren, CPT, MSC, assisted in data collection.

c. Funding: No funding was expended for this project during the preceding fiscal year.

d. Number of soldiers enrolled to date: 266

e. Number of subjects enrolled for reporting period: 266

Progress: As of this date, all subjects have been tested, the resulting profiles have been scored, and meetings have been held between the principal investigators and Dr. Butcher to discuss how to best present and use the obtained data. Dr. Butcher, who is restandardizing the MMPI on a national sample, has nearly completed his data gathering. The next step for the national restandardization is data analysis, which should be completed by the end of 1985. Additionally, special population norms are being developed. In recent discussions with Dr. Butcher, he believes that the Fort Gordon sample might be fruitfully combined with additional military samples currently being obtained and the combined results of the military samples presented as a special population study. The most suitable forum for presenting the results would be a paper at the 20th Annual Symposium on Recent Developments in the Use of the MMPI and the 9th International Conference on Personality Assessment. In order to develop such a paper, Drs. DeVore and Flowers have completed a comprehensive bibliography of all uses of the MMPI with military populations. It is anticipated that this bibliography will be published as a separate annotated bibliography as well as provide a useful review of literature with which to understand the new military norms being developed.

Detail Summary Sheet

Date: 2 Oct 84 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: May 78		Est Comp Date:
Principal Investigator(s) Kenneth Y. Gleitsmann, M.D., CPT, MC John E. Riffle, M.D., COL, MC John Pope, Jr., M.D., LTC, MC		Facility: DDEAMC
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words: Intraocular Lens Implant Ophthalmology Aphakia Surgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 84 Review Results Continue

Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.

Technical Approach: Currently accepted surgical techniques for cataract extraction and intraocular lens implantation using the operating microscope.

Number of subjects enrolled to date: 417

Number of subjects enrolled for reporting period: 91

Progress: The highest rate of complications is with the 91Z lens, which has been taken off the market, and the Anchor lens which is no longer used here. The lowest rate of complications is with the 34S posterior chamber lens. There has been a recent nationwide trend toward the use of posterior chamber lenses as opposed to anterior chamber intraocular lenses. It is anticipated that we will be doing predominately posterior chamber intraocular lens implantations in the future at DDEAMC.

Detail Summary Sheet

Date: 8 Aug 84 Prot No.: 82-57 Status: Terminated
 Title: Utilization of the Bascom Technique in the Treatment of Acute and Chronic Pilonidal Abscess Disease.

Start Date: Oct 82	Est Comp Date:
Principal Investigator(s) Kerrey B. Buser, M.D., CPT, MC Guillermo Quispe, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Surgery/General Surgery	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Nov 83 Review Results Continue

Study Objective: To ascertain if the application of the Bascom technique will decrease disability and/or hasten healing time in acute pilonidal disease.

Technical Approach: All acute and chronic pilonidal abscesses seen by the Surgical Service at DDEAMC are to be treated according to the techniques described by Dr. Bascom. The patients will be treated as outpatients. During duty hours, Dr. Buser and/or Dr. Quispe will see all patients included in this study and will provide treatment. The patients will be seen at least once a week until total healing has taken place. At the completion of the study, disability time and healing time will be assessed and a comparison will be made with Dr. Bascom's results.

Number of subjects enrolled to date: Four.

Number of subjects enrolled for reporting period: None

Progress: Principal investigator is no longer a resident in the Surgical Training program, staff investigator is now on teaching staff at WRAMC. Study is terminated.

Detail Summary Sheet

Date: 22 Oct 84 Prot No.: 83-5 Status: Completed
 Title: XM-72 Nonabsorbable Monofilament Suture.

Start Date: Jun 83	Est Comp Date:
Principal Investigator(s) Roberto H. Barja, M.D., COL, MC	Facility: DDEAMC
Dept/Svc: Surgery/Orthopedic	Associate Investigators: Orthopedic Staff Physicians
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Nov 83 Review Results Continue
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Study Objective: To compare XM-72 and Prolene sutures in terms of tissue reaction, efficacy and handling properties including suppleness, tissue drag and knotting properties, i.e., rundown and knot security.

Technical Approach: Fifty patients will be entered into the study at random. These will be both male and female requiring various surgical procedures. Half of the patients will be sutured with experimental suture and half with Prolene. Terminally ill patients will be excluded.

Subjects enrolled for reporting period: 15

Progress: Project was completed and all material forwarded to the home office in New York.

Detail Summary Sheet

Date: 4 Oct 84 Prot No.: 83-17 Status: Ongoing
 Title: Comparison of Efficacy of Metronidazole in an Animal Model.

Start Date: Feb 83		Est Comp Date:
Principal Investigator(s) William M. Steely, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Surgery Clinical Investigation		Associate Investigators: Ross S. Davies, M.D., COL, MC Richard W. Harris, CPT, MSC J. Bruce Arensman, DVM, MAJ, VC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To examine the effects of antibiotics on monomicrobial and polymicrobial abscesses in a rabbit model.

Technical Approach: Sterile plastic perforated capsules were implanted intraperitoneally into New Zealand white rabbits and held 6 weeks to become encased in a layer of connective tissue. An attempt was then made to treat the animals with metronidazole to determine penetration of the antibiotic in sterile capsule. An intravenous catheter in the jugular vein was inserted and maintained for dosing at a rate of 100 mg/kg/day every 8 hours for 7 days. Samples for serum concentrations and capsule fluid concentrations were obtained at 3 and 7 days. Metronidazole concentration was determined by high performance liquid chromatography.

Progress: Metronidazole was successfully infused into sterile plastic intraperitoneal chambers at a concentration of 10 mg/ml of fluid after one hour. Serum concentrations were approximately 20 mg/ml one hour after infusion. Studies are ongoing to determine the ability of metronidazole to penetrate capsule fluid containing B. fragilis and E. coli. This study is being done by the Microbiology Service at Department of Clinical Investigation and the Department of Surgery.

Detail Summary Sheet

Date: 30 Aug 84 Prot No.: 83-23 Status: Terminated
 Title: Solute Diuretic Effect of Endogenous Urea in Gastrointestinal Bleeder.

Start Date:		Est Comp Date:
Principal Investigator(s) Kerrey B. Buser, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Surgery Clinical Investigation		Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC James C. McPherson, III, PhD, DAC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the amount and the significance of water loss due to the urea solute diuresis in dogs.

Technical Approach:

Progress: Administratively terminated.

Detail Summary Sheet

Date: 15 Oct 84 Prot No.: 83-24 Status: Ongoing
 Title: Assessment of Vertical Banded Gastroplasty in Treatment of Morbid Obesity.

Start Date: Apr 83	Est Comp Date:
Principal Investigator(s) Ross S. Davies, M.D., COL, MC Robert Chadband, M.D., MAJ, MC David T. Armitage, M.D., COL, MC	Facility: DDEAMC
Dept/Svc: Surgery Medicine Psychiatry and Neurology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: To determine if vertical banded stapling is an effective treatment modality for morbid obesity, to determine its long term effectiveness and complications, and to determine if it will prevent the detrimental effects of morbid obesity.

Technical Approach: Weight loss post bypass will be studied in each patient and compared to average weight loss from other centers following the same procedure. Psychologic testing post-operative will be compared to pre-operative results to examine patient self-image pre and post weight loss.

Subjects enrolled to date: 29
 Subjects enrolled for reporting period: 17

Progress: Results are paralleling national studies with weight loss at 50 lbs/6 months and 100 lbs first year. No significant complications have occurred.

Detail Summary Sheet

Date: 17 Oct 84 Prot No.: 83-27 Status: Ongoing
 Title: Microsurgery Skill Lab.

Start Date: Nov 83		Est Comp Date:
Principal Investigator(s) Allan Goodrich, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Surgery/Orthopedic		Associate Investigators: Orthopedic Residents
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: In depth exposure to the principles and techniques of microsurgery in a laboratory setting - skills developed being transferable to clinical setting - may also stimulate interest in further research related to field of microsurgery.

Technical Approach: Monthly orthopedic rotation in microvascular surgery for residents with special emphasis on microvascular repair of rat femoral arteries.

Progress: Over the past year, each orthopedic resident spend three to five mornings for a full month mastering the instrumentation and technical skills requiring the use of the operative microscope performing microvascular repairs. This experience has proven to be extremely worthwhile from a teaching standpoint with direct application to surgical procedures performed in orthopedics specifically small vessel and nerve repair.

Detail Summary Sheet

Date 2 Oct 84		Prot No.: 83-30		Status: Terminated	
Title: Use of Spring Loaded Silastic Discs as a Prosthesis for Cervical Intervertebral Discs.					
Start Date: Jun 83			Est Comp Date:		
Principal Investigator(s) Nabil L. Muhanna, MAJ, MC			Facility: DDEAMC		
Dept/Svc: Surgery/Neurosurgery Clinical Investigation			Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To study the suitability of spring loaded silastic discs as a prosthesis for cervical intervertebral discs in the normal canine.

Technical Approach: Using a vertebral approach the vertebral bodies of C₂ through C₆ are exposed. Three intervertebral spaces are identified, the disc material is removed and a silastic prosthesis is inserted. Sutures are placed to secure the prosthesis, and the surgical site is closed. Healing and placement of the prosthesis is monitored by radiographic examination, and routine physical examinations. At approximately four months the animals will be sacrificed and the vertebral sites examined both grossly and histologically.

Progress: Four dogs were operated as per above technique with limited success as evaluated by x-ray and necropsy. Principal investigator has left the service and the study will not be continued. Recommend termination.

Detail Summary Sheet

Date: 23 Oct 84		Prot No.: 83-33		Status: Ongoing	
Title: Reflux Esophagitis in Morbid Obesity and the Effects of Vertical Banded Gastroplasty.					
Start Date: Jul 83			Est Comp Date:		
Principal Investigator(s)			Facility:		
Frank G. Opelka, CPT, MC			DDEAMC		
Ross S. Davies, COL, MC			Associate Investigators:		
Dept/Svc:			Surgery		
Key Words:			Periodic Review Results		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To evaluate the potential for reflux esophagitis in the morbidly obese patient, before and after vertical banded gastroplasty.

Technical Approach: In addition to a preoperative history and physical, each patient will be evaluated and scored for symptoms of gastroesophageal reflux according to the method of Iascone et al.

Subjects enrolled to date: 30

Subjects enrolled for reporting period: 26

Progress: So far of the patients studied there have been no complications from the monitoring techniques. Preoperatively, there has been no increased incidence of reflux both by history and by objective evaluation. Postoperatively, there has been no noted change in this pattern.

Detail Summary Sheet

Date: 2 Oct 84		Prot No.: 84-25		Status: Ongoing	
Title: Comparison of Thermography and Standard Techniques for Detection, Diagnosis and Tracing of Peripheral Vascular Disease and Disorders Marked by Altered Patterns of Peripheral Blood Flow.					
Start Date: Mar 84			Est Comp Date:		
Principal Investigator(s) Roberto H. Barja, MD, COL, MC Richard A. Sherman, PhD, CPT, MSC			Facility: DDEAMC		
Dept/Svc: Surgery/Orthopedics Clinical Investigation			Associate Investigators: Robert Anderson, MD, LTC, MC Larry Walker, MD, CPT, MC J. Allan Goodrich, MD, MAJ, MC Larry Donovan, MD, CPT, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the optimal utilization of thermography in Clinical evaluation of the vascular status of the affected area. This phase of the project is concentrating on correlating near surface blood flow patterns with reports of pain having varied diagnostic etiologies. The aim is to determine whether thermography is a more sensitive and objective method for initially diagnostic and subsequently tracking pain problems with vascular components than current methods.

Technical Approach: Subjects are recorded thermographically as soon as a patient meeting the eligibility criteria requests treatment. This forms a part of the regular work-up for diagnosis of pain in the Orthopedic Clinic. A series of recordings are made as the patient progresses through treatment and follow-up. The results are then compared with the results of the standard clinical evaluation.

Number of subjects enrolled to date: 49

Progress: No objective findings are available yet, but thermography appears to be a consistent, highly sensitive tool in many instances.

Detail Summary Sheet

Date: 16 Oct 84	Prot No.: 84-41	Status: Ongoing
Title: Clinical Investigation of the Long Term Effects of Arthroscopic Knee Surgery in the Military Hospital Population.		
Start Date:	Est Comp Date:	
Principal Investigator(s) LeRoy R. Fullerton, M.D., LTC, MC	Facility: DDEAMC	
Dept/Svc: Surgery/Orthopedic Surgery	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To analyze the results in patients treated with knee surgery under arthroscopic surgical control during the period 1 January 1980 to 15 July 1983 at Ft Benning, GA.

Technical Approach:

Progress: Awaiting questionnaires from reproduction section. Awaiting typing of letters and envelopes.

Detail Summary Sheet

Date: 16 Oct 84 Prot No.: 84-42 Status: Ongoing
 Title: Clinical Investigation of Femoral Neck Stress Fractures.

Start Date:	Est Comp Date:
Principal Investigator(s) LeRoy R. Fullerton, M.D., LTC, MC	Facility: DDEAMC
Dept/Svc: Surgery/Orthopedic Surgery	Associate Investigators: Harry Snowdy, MD, Orthopedic Dept, Univ of Texas, San Antonio
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To analyze the natural history of a group of patients who sustained femoral neck stress fractures while training at Ft Benning, GA during the period July 1979 to July 1983.

Technical Approach:

Progress: Awaiting questionnaires from reproduction section. Awaiting typing of letters and envelopes.

Detail Summary Sheet

Date: 2 Oct 84 Prot No.: 84-45 Status: Suspended
 Title: Endoscopic Training Lab.

Start Date: Apr 84		Est Comp Date:
Principal Investigator(s) Richard M. Satava, M.D., LTC, MC		Facility: DDEAMC
Dept/Svc: Surgery Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Entry level acquaintance with endoscopic skills. The performance of both diagnostic and therapeutic endoscopy on laboratory animals (dogs) in order to develop clinical skills in endoscopy. Also, creation of clinical gastrointestinal entities (pathology, surgical procedures) which can be studied endoscopically for the purpose of training and research.

Progress: There are currently 9 of the anticipated 15 animal models completed and being utilized for surgical resident endoscopy training; these include models of Nissen fundoplication, gastric polyps, antrectomy and Bilroth 1 anastomosis, subtotal gastric resection with Bilroth 2 anastomosis, vertical banded gastroplasty, cholecystoduodenostomy, gastroenterostomy, and right hemicolectomy. Three additional animals died of post-operative complications (pneumonia, uremia, and hemorrhage from an intra-abdominal abscess).

Training of surgical residents has begun, with initiation of the Fundamentals of Endoscopy session with residents on the PGY 3 level. Due to the retirement of the Chief, Animal Support Service and the concomittant lag until arrival of a new chief, this phase has been progressing slower than anticipated; however, as the laboratory returns to full productivity, the program will resume. In addition, new essential endoscopy equipment which was approved for the MEDCASE 1985 budget has yet to arrive. Receipt of this equipment will greatly facilitate the program.

Contact has been made with directors of Surgical Endoscopy in other Army Medical Centers with a view to presenting a Surgical Endoscopic Symposium, which would utilize the facilities of the laboratory and the prepared animal models as an integral part of the symposium.

Detail Summary Sheet

Date: 2 Oct 84 Prot No.: 84-46 Status: Suspended
 Title: Rectal Mucosectomy With Hydrostatic Dissection.

Start Date: May 84		Est Comp Date:
Principal Investigator(s) Richard M. Satava, M.D., LTC, MC		Facility: DDEAMC
Dept/Svc: Surgery Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To develop a technique of dissecting the rectal mucosa from the underlying muscularis mucosa without excessive blood loss.

Progress: One animal (dog) was used to develop the technique. Post-operative incontinence, in spite of a normal resting anal sphincter tone was noted; therefore, prolonged observation (8 weeks) revealed that incontinence did not clear in spite of various maneuvers to control the diet. In man, diarrhea can persist from 6 to 8 weeks post-operatively and usually resolves spontaneously. Rarely does man have post-operative incontinence.

Current review of the protocol before further operative procedures are performed has resulted in consideration of a different animal model (porcine, and in particular, mini-pig); however, to date this animal model has not been received in the laboratory. Most other possible animal models are ruminants (with markedly different gastrointestinal anatomy from man) which make them less suitable than a mini-pig for models. Other porcine models, of less expense, are also under consideration.

Technically, the procedure of rectal mucosectomy in the above noted dog was performed with excellent results. It is anticipated that, as soon as a suitable model is achieved, the investigation can be completed within a 6 month time frame.

Detail Summary Sheet

Date: 2 Oct 84		Prot No.: 84-47		Status: Ongoing	
Title: Omental Splenic Autotransplantation and Near Total Splenectomy - Protective Effect Against Pneumococcal Bacteremia.					
Start Date:			Est Comp Date: Jan 85		
Principal Investigator(s)			Facility:		
Richard M. Satava, M.D., LTC, MC			DDEAMC		
William M. Steely, M.D., LTC, MC			Associate Investigators:		
Dept/Svc:			Richard W. Harris, CPT(P), MSC		
Surgery					
Clinical Investigation					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: a) To compare two different methods of splenic tissue preservation, and b) to establish the protective effect of a small segment of spleen attached to its own vascular pedicle (near total splenectomy) and autotransplanted spleen against a challenge S. pneumonia.

Progress: Phase I. Initial study consisting of three groups of eight rats each has been completed. The respective groups were total splenectomy for one, the second group was near total splenectomy and the third group was total splenectomy with splenic autotransplantation into an omental pouch. The rats in the transplanted groups were sacrificed at 12 weeks finding splenic tissue near the area of omental pouch which had been constructed at the initial surgery. This was confirmed by histologic examination of the tissue. The remainder of the animals will be used as an initial group to be challenged with strep pneumonia for the determination of the LD50 as soon as this organism is prepared.

Phase II. CPT Harris is evaluating pneumococcal organisms at this time and running them through the animals multiple times to ensure encapsulation. The actual project itself is underway, each group of 24 rats to include a control group of sham operated rats, a second group of total splenectomized rats, a third group of partial splenectomized rats and a fourth group of autotransplanted spleen rats are all completed. This is a total of approximately 100 Sprague-Dawley rats. These rats will be used in the actual experiment. All the Sprague-Dawley rats which will be used in the actual project are operated on and are awaiting challenge at approximately 12 weeks with pneumococci. There will be another group of rats operated for total splenectomy of a number to be determined that will be necessary to determine our LD50 for the strep pneumonia once the appropriate strain has been isolated. This is an ongoing project, and it should be completed within three to four months.

Detail Summary Sheet

Date: 5 Oct 84	Prot No.: 84-72	Status: Ongoing
Title: Effects of Epinephrine on Epidural Fentanyl and Hydromorphone for Postoperative Analgesia.		
Start Date: Sep 84	Est Comp Date: Summer 85	
Principal Investigator(s) Edson O. Parker, III, LTC, MC	Facility: DDEAMC	
Dept/Svc: Surgery/Anesthesia	Associate Investigators: Sheryl J. Bartell, MAJ, MC G. Lee Brookshire, CPT, MC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective: To assess the effects on the intensity and duration of postoperative analgesia and any other known side effects of epidural narcotics by adding epinephrine to a solution of either fentanyl or hydromorphone injected in the epidural space.		

Technical Approach: After the drug is injected, the epidural catheter will be removed from the back. Each patient will then be observed by one of the investigators after the injections, each 15 minutes for the first hour, then each hour for the next 7 hours for fentanyl and 15 hours for hydromorphone. Observations will be made and recorded for absence, presence, degree of, and treatment for abnormalities in blood pressure, heart rate, respiratory rate, pain, nausea, vomiting, pruritus, somnolence and respiratory depression.

Number of subjects enrolled to date: 7
Adverse effects: None

Progress: Study started in Sep, no reportable data.

Detail Summary Sheet

Date: 15 Oct 84 Prot No.: 83-21 Status: Terminated
 Title: Married Couples Group Therapy: A Clinical Investigation

Start Date: Nov 83	Est Comp Date:
Principal Investigator(s) James L. Maury, MAJ, DSW, MSC Shirley M. Walley, Graduate Student	Facility: DDEAMC
Dept/Svc: Social Work Service Family Practice	Associate Investigators: Ronald J. Platte, LTC, PhD, MSC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Mar 84 Review Results Terminate

Study Objective: To measure the effect of a married couples group therapy on marital interaction.

Technical Approach: Five married couples referred by their family physician for marital therapy will initially be seen alone as a couple in order to: obtain their consent to participate; establish a therapeutic relationship; identify basic demographic data; and administer the marital adjustment scale. All five couples will then be seen together in group therapy for 1½ hours once per week for eight weeks. At the end of eight weeks, each couple will be interviewed alone and readministered the marital adjustment scale. The data will be analyzed using standard social science research statistics.

Progress: Unable to initiate study; terminate.

Detail Summary Sheet

Date: 10 Oct 84 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: Nov 80	Est Comp Date:
Principal Investigator(s) Thomas W. Grabow, M.D., LTC, MC John M. Hope, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Surgery/Ophthalmology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Feb 84 Review Results Continue
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Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of intraocular lens. Presently, the lenses used have been a Tennant/Anchor Anterior Chamber Lens, a Tennant Anchorflex II Lens, a Pannu Anterior/Posterior Chamber Lens, an IOLAB J-Loop Lens, the McGhan 34S Modified Sheets Lens and a Liteflex Lens.

Number of subjects enrolled to date: 285
 Number of subjects enrolled for reporting period: 82

Progress: Regular follow-up continues on all patients consistent with the guidelines given by the manufacturers of the implants.

Detail Summary Sheet

Date: 10 Oct 84 Prot No.: 79-25 Status: Terminated
 Title: The Effect of Guaifenesin in the Treatment of Middle Ear Effusion: A Double Blind Study.

Start Date: Nov 80		Est Comp Date:
Principal Investigator(s) Gregory H. Blake, M.D., MAJ, MC		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators: Dale A. Carroll, M.D., MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Feb 84 Review Results Continue

Study Objective: To determine whether guaifenesin, a mucolytic agent has a place in the management of middle ear effusion.

Technical Approach: The study is a double blind protocol looking at children aged 2-16 years who have middle ear effusion. Middle ear effusion is diagnosed by clinical history, otoscopic exam, and audiology evaluation. Audiologic criteria are a Type B tympanogram or two of the following: a difference between air and bone conduction hearing threshold level of .15 dB or more on three test frequencies; a maximum compliance change peak which is negatively displaced 100 mm or more from ambient air; and a static middle ear compliance less than 0.26 ml. Half of those patients agreeing to enter the study will be given guaifenesin and the other half the base of guaifenesin. Patients will be followed for clinical and audiologic improvement at two and four weeks.

Subjects enrolled to date: 12
 Subjects enrolled for reporting period: None.

Progress: Terminate study. Principal investigator has ETS'd and Dr. Carroll does not wish to continue the study.

Detail Summary Sheet

Date: 10 Oct 84		Prot No.: 82-41		Status: Ongoing	
Title: Correction of Myopia Using the Fading Technique.					
Start Date: May 82			Est Comp Date:		
Principal Investigator(s)			Facility:		
Glenn C. Griffiths, M.D., CPT, MC			USA MEDDAC, Ft Benning, GA		
Dept/Svc:			Associate Investigators:		
Family Practice			Thomas W. Grabow, M.D., LTC, MC		
Surgery/Ophthalmology, Optometry			William T. Nimmons, O.D., CPT, MSC		
Key Words:					
Accumulative MEDCASE		Est Accumulative		Periodic Feb 84	
Cost:		OMA Cost:		Review Results Continue	

Study Objective: To determine if training the eye to focus at progressively greater distances results in improvement in myopia.

Technical Approach:

1. Test visual parameters of subjects.
2. Subjects begin fading technique using lens system.
3. Vision testing 3 days per week.
4. Retest visual parameters of subjects at 6 and 12 months after training completed.

Progress: Due to completion of 3rd year residency and military training, this study has not progressed during the reporting period. Principal investigator has been assigned to this MEDDAC after graduation and will continue the study.

Detail Summary Sheet

Date: 10 Oct 84 Prot No.: 83-1 Status: Ongoing
 Title: Application of Screening Procedure to Determine the Etiology of Microcytosis With or Without Anemia.

Start Date: Oct 82	Est Comp Date:
Principal Investigator(s) Ronald G. Albright, Jr., M.D., MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Feb 84 Review Results Continue

Study Objective: To evaluate the ability of simple calculations made from information found on the routine Coulter CBC slip to predict the etiology of microcytosis with or without anemia.

Technical Approach: Chart review.

Progress: Thirty charts reviewed. Data collection in progress.

Detail Summary Sheet

Date: 10 Oct 84 Prot No.: 83-2 Status: Ongoing
 Title: Remarried Families: Adaptability and Cohesion.

Start Date: Nov 82	Est Comp Date:
Principal Investigator(s) Perry L. Wolf, III, CPT, MSC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Social Work Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Feb 84 Review Results Continue

Study Objective: To study the relationship between family structure and family adaptability and cohesion. The relationship of the intervening variables -- discipline, mythology, and loss -- with adaptability and cohesion will be studied. Role theory and family systems theory will provide a theoretical framework.

Technical Approach: This study will investigate the psychological meaning of adolescent attributes to his/her biological parent and step-parent by comparing the adolescent's appraisal of them along the lines of evaluation, activity, and potency. Each family structure will include a biological mother, her biological child and either a biological father or a step-father. The major independent variable in this study will be defined as family membership in REM family or a biological parent family. Four instruments will be used to collect data on the other study variables.

Progress:

1. Three chapters of report written.
2. An instrument to measure REM family discipline, myths, and reaction to loss has been developed and its content validity established.
3. Waiting for final approval of my research committee at Catholic University to begin data gathering on families.

Detail Summary Sheet

Date: 10 Oct 84 Prot No.: 83-3 Status: Terminated
 Title: Otitis Media With Effusions: The Efficacy of Vibramycin and a Non-tapering Short Course Prednisone in Adults.

Start Date:	Est Comp Date:
Principal Investigator(s) Gregory H. Blake, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice	Associate Investigators: Frank S. Celestino, M.D., CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Feb 84 Review Results Continue

Study Objective: To determine the efficacy of steroids in the treatment of otitis media with effusion in adults.

Technical Approach: Double-blind controlled crossover clinical trial in which 30 active duty soldiers with otitis media with effusion will be studied. Subjects meeting inclusion criteria will be randomly placed in the treatment group or control group by the pharmacist.

Progress: Terminate. Both the principal and associate investigators have ETS'd.

Detail Summary Sheet

Date: 10 Oct 84 Prot No.: 83-10 Status: Terminated
 Title: The Anion Gap in Normal Human Pregnancy.

Start Date: Nov 82		Est Comp Date: Jun 84
Principal Investigator(s) William D. Paulson, M.D., MAJ, MC		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Medicine, OB-GYN, Pathology		Associate Investigators: John Sautlz, M.D., MAJ, MC Glenn Griffiths, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Feb 84 Review Results Continue

Study Objective: To determine the normal reference value for the anion gap in human pregnancy.

Technical Approach: Seventy-five patients will be enrolled in the study prior to their Obstetrics Clinic visit at 34 weeks. Venous serum will be obtained at the time of entry to the study, then at 34 weeks into the pregnancy, and three months postpartum. Analysis of variance will be used for repeated measures in the same subject to detect differences in the two data groups.

Progress: None. Principal investigator has PCS'd. Study terminated.

Detail Summary Sheet

Date: 10 Oct 84		Prot No.: 83-42		Status: Completed	
Title: Skinfold Measurements and the Percentage of Body Fat Differences Between Black and Caucasian Male Soldiers.					
Start Date:		Est Comp Date: Dec 83			
Principal Investigator(s)		Facility:			
Karen P. Hobson, MAJ, AMSC		USA MEDDAC, Ft Benning, GA			
Dept/Svc:		Associate Investigators:			
Nutrition Clinic					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To 1) determine if there is a significant difference between the skinfold measurements taken on Black soldiers as compared to Caucasian soldiers; 2) determine the need for a race-specific standard of body fat percentage to be used in the evaluation of overweight soldiers; 3) evaluate the age factor differences in body fat percentage in the older age groups.

Technical Approach: One-time skin fold measurements of male soldiers.

Number of subjects enrolled for reporting period: 302

Number of subjects enrolled to date: 302

Progress: Soldiers were measured with a Lange Skinfold Caliper at four body sites (triceps, biceps, subscapular and iliac crest). The measurements were compared statistically for differences between the black soldier and the white soldier. It was hypothesized that (a) there is no significant difference between skin-fold measurements taken from black soldiers and those taken from white soldiers, and (b) there is no significant difference in percent of body fat between black and white soldiers as determined by the established method. Height, weight and four skinfold sites were measure on 302 male soldiers (151 black, 151 white) with percent body fat calculated from the sum of the four site measurements. These measurements were grouped in age ranges and compared by race for normal weight trainees and overweight soldiers.

The black soldiers consistently had smaller skinfold measurements, and averaged 2% less body fat than the white soldiers. A significant difference ($p < .01$) was found for triceps, biceps and iliac crest skinfold thicknesses between the two races. Overweight black soldiers met the Army established maximum percent body fat twice as often as overweight white soldiers, 16 out of 38 versus 7 out of 38 respectively.

This study indicates that the black soldier had smaller skinfolds and averaged lower percent body fat than the white soldier and that the overweight black soldier was not discriminated against when the sum of four skinfold methods was used to determine body fat percentage. As the weight and height for each race within the groups was similar, the smaller skinfold measurements, and, therefore, lower percent body fat of black males provides further support for racial differences in body composition and/or distribution of muscle and subcutaneous fat.

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CLINICAL INVESTIGATION PROGRAM RCS MED-300 (RI)(U)
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GA DEPT OF CLINICAL INVESTIGATION K M PLOWMAN OCT 84

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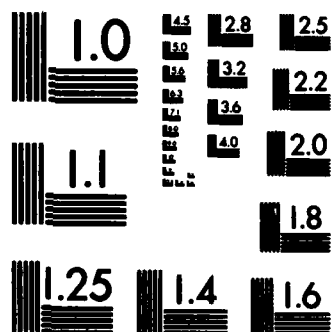
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MICROCOPY RESOLUTION TEST CHART
NATIONAL BUREAU OF STANDARDS-1963-A

Detail Summary Sheet

Date: 10 Oct 84		Prot No.: 84-7		Status: Ongoing	
Title: How do Patients Choose Their Physician? The Effect of Patient Knowledge of Family Practice on Their Choice of Physicians					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
John W. Saultz, M.D., CPT, MC			USA MEDDAC, Ft Benning, GA		
Dept/Svc:			Associate Investigators:		
Family Practice			James B. Wright, M.D., MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: This study is designed to measure the impact of pre-printed information sheets on whether a family chooses to join Family Practice or not. To gather basic data on the characteristics, i.e., background, education, training of those individuals who do choose to sign up for Family Practice.

Technical Approach: 1) Control group given no information. 2) Group given questionnaire only. 3) Group given questionnaire and pre-written information about Family Practice by American Academy of Family Physicians.

Progress: Data collected and now being analyzed.

Detail Summary Sheet

Date: 10 Oct 84		Prot No.: 84-22		Status: Terminated	
Title: Cryotherapy in the Management of Acute Ankle Sprains - A Comparative Study.					
Start Date: Feb 84			Est Comp Date:		
Principal Investigator(s) Alfred B. Woodhead, CPT, AMSC George Gumann, CPT, MC			Facility: USA MEDDAC, Ft Benning, GA		
Dept/Svc: Surgery/Physical Therapy and Podiatry			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To compare the effectiveness of the Jobst Cryotemp to that of ice in the reduction of the symptoms of acute ankle sprains.

Technical Approach: "One shot" case study.

Manpower: Two principal investigators.

Funding: None.

Number of subjects enrolled to date: 8

Number of subjects enrolled for reporting period: 8

No adverse reactions.

Progress: Only two subjects were followed to recovery. A logistical problem developed as pressure was placed on the subjects to return to duty as soon as possible. Thus, all but two subjects failed to return for treatment. This was especially true in the case of trainees since they were threatened with recycling, thus the study was terminated due to the above reasons and the fact that the primary investigator was about to ETS.

Detail Summary Sheet

Date: 10 Oct 84 Prot No.: 84-23 Status: Ongoing
 Title: Smoking and Attrition in Infantry One Station Unit Training (OSUT).

Start Date: Feb 84	Est Comp Date:
Principal Investigator(s) Gregory H. Blake, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice	Associate Investigators: John A. Parker, Jr., MD, MAJ, MC Wayne G. Stanley, MD, CPT, MC Frederick N. Dyer, PhD, CPT, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To determine whether smoking adversely affects successful completion of Infantry One Station Unit Training (OSUT).

Technical Approach: Administrative questionnaires regarding smoking given to troops of Infantry One Station Unit Training (OSUT). These troops will be followed until the conclusion of OSUT.

Progress: Currently gathering data.

Detail Summary Sheet

Date: 15 Oct 84 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: Oct 81	Est Comp Date:
Principal Investigator(s) Ramsey Tarabishy, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Campbell, KY
Dept/Svc: Surgery/Ophthalmology	Associate Investigators: Richard B. Phinney, M.D. CPT, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: To provide to cataract patients the latest development in ophthalmic surgery concerning the correction of surgical aphakia.

Technical Approach: Intracapsular or extracapsular cataract extraction followed by the implantation of an anterior chamber lens.

Cost per lens: \$360 each.

Subjects enrolled to date: 27

Subjects enrolled for the reporting period: 13

Progress: Lenses used: Pannu Anterior Chamber Lenses Model AC/PC55. No complications related to lens implantation noted. All patients have attained increased acuity better than 20/30.

Detail Summary Sheet

Date: 19 Oct 84		Prot No.: 83-29		Status: Terminate	
Title: Study of the Relationship Between Ambient, Personal, Expired Air Samples and Carboxyhemoglobin Levels Among Personnel Intermittently Exposed to Carbon Monoxide.					
Start Date: May 83			Est Comp Date:		
Principal Investigator(s) Jory S. Simmons, M.D. Larry C. Brantley			Facility: USA MEDDAC Ft Campbell, KY		
Dept/Svc: Preventive Medicine Activity			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine 1) if expired air serves as an accurate measure of blood carboxyhemoglobin levels; 2) if there is a difference in the measurement of carboxyhemoglobin levels and carbon monoxide expired levels between smokers and non-smokers; 3) if there is a significant relationship between expired breath, personal air samples, and ambient air samples.

Technical Approach: Determination of ambient air and expired breath samples using a calibrated Ecolyzer carbon monoxide instrument. Laboratory analysis of carboxyhemoglobin by Co-Oximeter.

Progress: Six subjects enrolled through FY 83.

Terminate, investigator departed and failed to submit a report.

Detail Summary Sheet

Date: 30 Aug 84 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: Jul 81		Est Comp Date:
Principal Investigator(s) Norman T. Byers, M.D., LTC, MC		Facility: USA MEDDAC, Ft Jackson, SC
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 84 Review Results Continue
Study Objective: Insertion in selected patients of Tennant Anterior Chamber Anchor Lens.		

Technical Approach: Using routine intracapsular cataract techniques, the lens would be inserted prior to final closure of the wound.

Subjects enrolled to date: 187
 Subjects enrolled for reporting period: 133

Progress: No complication.

Detail Summary Sheet

Date: 30 Aug 84 Prot No.: 83-40 Status: Completed
 Title: Psychotropic Medication Education Needs of Parents and Children.

Start Date: Oct 83	Est Comp Date:
Principal Investigator(s) Patrick Butterfield, M.D. Christopher B. White, M.D., CPT, MC	Facility: USA MEDDAC Ft Jackson, SC
Dept/Svc: Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To determine the knowledge base parents and children regarding psychostimulants has been the objective of this portion of the study. The objective to determine what primary health care providers think are important considerations in prescribing of psychostimulants for children has been completed in a previous study not associated with Fort Jackson.

Technical Approach: The parents of, and children taking, psychostimulant medications will be interviewed using a structured interview format and a questionnaire about their knowledge about psychostimulants and what information about psychostimulants they would like to know. No manpower or funding are utilized from the US Army. To date 20 children and their parent(s) have been interviewed according to the protocol.

Progress: Since September 1983, we have interviewed 20 children and their parent(s) utilizing the structured interview format and protocol. This number is the result of an initial contact of names we obtained from the pharmacy at Moncrief Army Hospital. Other potential subjects that were contacted declined to volunteer for this project. To date the results of this study have not been presented at any meeting, nor have they been submitted for publication. The subjects from Moncrief Army Hospital will be combined with subjects from the William S. Hall Psychiatric Institute. We have prepared an abstract and submitted it for presentation at the 36th Annual Meeting of the American Association of Psychiatric Services for Children in Orlando, Florida on February 1 and 2, 1985.

Detail Summary Sheet

Date: 30 Aug 84		Prot No.: 83-41		Status: Terminated	
Title: COPD: The Effectiveness in Promotion of Social Support and Reduction in Health Care Settings.					
Start Date: Oct 83			Est Comp Date:		
Principal Investigator(s) Evelyn A. Swenson-Britt, CPT, ANC Ann Preble, CPT, ANC			Facility: USA MEDDAC Ft Jackson, SC		
Dept/Svc: Nursing			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine what the effect of a support group is on health care usage and on social support in these COPD patients' lives.

Technical Approach:

Progress: Terminated, investigators departed Ft Jackson and failed to submit a report.

Detail Summary Sheet

Date: 11 Sep 84		Prot No.: 83-39		Status: Completed	
Title: Structural Foot and Ankle Abnormalities as a Determining Factor for Stress Fracture Development.					
Start Date: Oct 84			Est Comp Date:		
Principal Investigator(s) Lauren Y. Hughes, CPT, AMSC			Facility: USA MEDDAC, Ft McClellan, AL		
Dept/Svc: Physical Therapy			Associate Investigators:		
Key Words: Stress fracture					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To note if basic trainees with certain biomechanical malformations are pre-disposed to obtaining stress fractures.					

Technical Approach: Subjects were soldiers developing metatarsal stress fractures. Two groups were utilized in this study, 47 soldiers with radiologically positive metatarsal stress fractures/reactions and 47 soldiers in a control group which was matched identically to the stress fracture group in sex, race, week of training and age was within five years. The measures of forefoot varus, dorsiflexion with the knee extended and rearfoot valgus were recorded for each subject.

Progress: Patients with a tight gastrocnemius and soleus had a 4.6:1 chance of developing a stress reaction. Significant to $X^2=.995$. Tight plantarflexor were those with dorsiflexion $< 0^\circ$. Patients with $\geq 1^\circ$ forefoot varus were found to have 8.3:1 odds of developing a stress fracture $X^2=.995$. Rearfoot valgus was not found to be a significant pre-determiner of stress fracture development.

Conclusion: patients with tight plantarflexors and/or forefoot varus are much more likely to develop stress fractures.

"Biomechanical Analysis of the Foot and Ankle for Predisposition to Developing Stress Fractures." Submitted to Journal of Orthopaedic and Sports Physical Medicine.

Detail Summary Sheet

Date: 21 Oct 84 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: Oct 80		Est Comp Date:
Principal Investigator(s) Jimmy Carter, M.D., LTC, MC William G. Carey, M.D., MAJ, MC		Facility: USA MEDDAC, Ft Rucker, AL
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words: Intraocular Lens Aphakia Implant Surgery Ophthalmology		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: The objective of the ongoing FDA study is to determine the safety of the intraocular lens implant in the human eye.

Technical Approach: In all primary implants during this period, the extracapsular cataract approach was used. A style 20 posterior chamber lens manufactured by Surgidev Corporation was placed in the posterior chamber. In all secondary implants, the style 10 anterior chamber lens, by Surgidev Corporation, was used.

Subjects enrolled to date: 184
 Subjects enrolled for reporting period: 81

Progress: During the reporting period, 76 posterior chamber and seven anterior chamber lenses were implanted. No eyes were lost at surgery or in the subsequent postop period. There was no pseudophakic bullous keratopathy sufficient to necessitate a corneal transplant. Opacification of the posterior lens capsule is certainly a progressive problem, but during the first year 10% only need a dissection of the capsule. Approximately one-half of all ECCE's are expected to need dissection over the next five years. There were no retinal detachments in patients operated on during this period. The incidence of persistent cystoid macular edema reducing functional vision to less than 20/40 was 4%.

In summary, this was a period wherein proven techniques were used with excellent success. Minimal complications were encountered.

Detail Summary Sheet

Date: 10 Oct 84 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date:	Est Comp Date:
Principal Investigator(s) Charles S. Tressler, MD, CPT, MC	Facility: USA MEDDAC, Ft Stewart, GA
Dept/Svc: Surgery/Ophthalmology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of intraocular lens.

Number of subjects enrolled to date: 0

Progress: None, investigator locally approved in Sep 84.

Detail Summary Sheet

Date: 5 Oct 84 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: Oct 82	Est Comp Date:
Principal Investigator(s) Ruben Orillac, M.D.	Facility: USA MEDDAC Panama
Dept/Svc: Surgery/Ophthalmology	Associate Investigators: Jerry D. Harrell, M.D., COL, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.

Technical Approach: Currently accepted surgical techniques for cataract extraction and intraocular lens implantation using the operating microscope.

Number of subjects enrolled to date: 69

Number of subjects enrolled for reporting period: 31

Progress: Of the 31 implants performed for the reporting period, 10 were secondary lens implants. Twenty-seven were Surgidev lenses, the other four were Tennant lenses from Precision-Cosmet. All were anterior chamber. There were two complications: one iridectomy which cleared spontaneously; the second was a vitritis that was treated with steroids and cleared without further problems.

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